Pharsight
A Certara™ Company

Getting Started Guide

Phoenix™ WinNonlin® 6.1

Phoenix™ Connect 1.1

Phoenix™ NLME 1.0

Phoenix™

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LAPACK

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Contents

Chapter 1 **Installation 1**
Pharsight contact information 1
System and hardware requirements 2
Installing Phoenix 5
Modifying, updating, or removing a Phoenix installation 14
Configuring Phoenix for international use 15
Opening TCP ports for MPICH2 16

Chapter 2 **Licensing 19**
Phoenix Licensing Service 19
License key code types 20
Product and authorization codes 20
Plug-in licenses 21
WinNonlin 5.2.1 license holders 24
License Activation 25
Setting up a license server 30
License Management 31
License Server Management 33

Chapter 3 **Testing the Installation 35**
Start Phoenix and create a new project 35
Confirm license installation 36
Confirm plug-in startup 37
Import a data set 37
Create a plot 38
Create a table 39

Confirm model functions 43
Noncompartmental analysis 43
Pharmacokinetic modeling 50
Bioequivalence 55

Chapter 4 **The Phoenix User Interface 63**
Phoenix User Interface 63
Phoenix Menu Options 64
Main menu options 65
Toolbar buttons 65
Phoenix Panels and Tabs 67
Object Browser panel 67
Diagram tab 68
Setup tab 69
Results tab 70
Verification tab 71
Information tab 72
History Tab 73

Chapter 5 **Phoenix Concepts 75**
Introduction 75
Phoenix Architectural Overview 75
Phoenix Terminology 76
Phoenix Work Concepts 80
Projects 80
Workflows 81
Operational Objects 83
Templates 85
Data 86

Index 89

Chapter 1

Installation

Installing the Phoenix Platform

The Getting Started Guide contains installation and licensing instructions for both Phoenix WinNonlin and Phoenix Connect. The generic term Phoenix is used in this guide to simplify terminology.

This chapter contains the following topics:

» "Pharsight contact information" on page 1

» "System and hardware requirements" on page 2

» "Installing Phoenix" on page 5

» "Modifying, updating, or removing a Phoenix installation" on page 14

» "Configuring Phoenix for international use" on page 15

» "Opening TCP ports for MPICH2" on page 16

Pharsight contact information

Please consult the documentation to address questions. If further assistance is needed, then contact Pharsight customer support.

Customer support	
Email	support@pharsight.com
Web	www.pharsight.com/support/support_sflogin.php
Phone	+1-919-852-4620
Fax	+1-919-859-6871

Customer support	
Post	Pharsight Corporation 5625 Dillard Drive, Suite 205 Cary, North Carolina 27518

Contact Pharsight sales for purchases, license renewals and product upgrades.

Sales	
Email	sales@pharsight.com
Phone	+1-888-708-7444 (US only) +1-919-852-4685 (International)
Fax	+1-650-314-3811

For licensing issues, including sales and technical support, use the following contact information.

Licensing sales and support	
Email	licensing@pharsight.com
Phone	+1-919-852-4610

System and hardware requirements

Phoenix is a software platform built on the Microsoft .NET 2.0 framework. It uses the MinGW (Minimalist GNU for Windows) compiler to create PML (Phoenix Modeling Language) models. Phoenix also uses MPICH2 to allow usage of multiple CPUs and CPU cores. All software prerequisites needed to use basic Phoenix functions are included in the Phoenix installation file. Extended Phoenix functions have additional software requirements.

Required software

» Microsoft® Windows® Installer 3.1.

– The installer can be downloaded through the Microsoft Update service or by downloading the Windows Installer 3.1 redistributable from the Microsoft download page.

Supported operating systems

The following operating systems have been tested to ensure they are compatible the Phoenix platform:

English language versions	Japanese language versions
Windows 2000 SP4	Windows 2000 SP4
Windows XP Pro SP3	Windows XP Pro SP3
Windows 2003 Citrix Server	Windows 2003 Citrix Server
Windows Vista 32 bit*	

*Phoenix is not officially supported on Windows Vista 64 bit.

Supported third party software

Supported Microsoft Office versions for the Word Export and Edit in Excel features.

English language versions	
Supported software version	**Tested operating systems**
Microsoft Office 2000	Windows 2000 SP4
Microsoft Office XP	Windows XP Pro SP3
Microsoft Office 2003	Windows XP Pro SP3 Windows 2003 Citrix Server
Microsoft Office 2007	Windows Vista 32 bit
Japanese language versions	
Supported software version	**Tested operating systems**
Microsoft Office 2003	Windows 2003 Citrix Server
Microsoft Office XP	Windows 2000 SP4 Windows XP Pro SP3

Other supported third party software for Phoenix plug-ins:

Phoenix Plug-in	Supported software versions	Tested operating systems
NONMEM Shell	NONMEM 5	Windows 2000 SP4 Windows XP Pro SP3
	NONMEM 6	Windows Vista 32 bit
SAS Shell	SAS 9.1	Windows 2000 SP4 Windows XP Pro SP3 Windows Vista 32 bit
SigmaPlot Shell	SigmaPlot 9.0.1	Windows 2003 Citrix Server
	SigmaPlot 10	Windows XP Pro SP3
	SigmaPlot 11.1	Windows Vista 32 bit Windows XP Pro SP3 Japanese version
S-PLUS Dataframe Import S-PLUS Script S-PLUS Worksheet Export	S-PLUS 6.2	Windows 2000 SP4
	S-PLUS 7.0	Windows XP Pro SP3 Windows 2003 Citrix Server
	S-PLUS 8.0	Windows Vista 32 bit Windows XP Pro SP3 Japanese version

Supported Pharsight software

Software	Requirements
PKS (Pharsight Knowledgebase Server) 4.0	See the PKS 4.0 Release Notes for a list of supported and tested software and operating systems.
PKS Reporter 1.3.1*	See the PKS Reporter 1.3.1 Release Notes for a list of supported and tested software and operating systems.

*When used in conjunction with PKS 4.0. Phoenix does not interact directly with PKS Reporter.

Phoenix can coexist with all current Pharsight software, including WinNonlin 5.2.1 with or without the IVIVC Toolkit.

Hardware requirements

Minimum Hardware requirements	
Item	**Requirement**
Processor	Intel Pentium 4 2.8 Ghz. or a CPU of EQUIVALENT processing power
RAM	1 gigabyte RAM
Harddrive space	300 megabytes free

Installing Phoenix

The instructions for installing Phoenix WinNonlin, Phoenix Connect, and Phoenix NLME are the same.

Before installation:

The following steps are optional and only apply if S-PLUS is going to be used with Phoenix but has not yet been installed.

1. If S-PLUS or later is not already installed then install S-PLUS according to the instructions on the S-PLUS installation CD.
2. Add the directory path to the S-PLUS installation to the System variables Path statement.
   - For example, if S-PLUS 7.0 is installed in the default location, then the System variable Path statement must include the line `C:\Program Files\Insightful\splus70\cmd`.
3. For more on editing System variables, refer to this Microsoft Knowledgebase article.

Installation notes:

» If Phoenix is being installed on a computer that uses Windows Vista, see "Windows Vista installation" on page 14 for post-installation instructions.

» If Phoenix is being installed on a computer that uses Windows 2003 Citrix Server, see "Windows 2003 Citrix Server installation" on page 14 for post-installation instructions.

» If Phoenix is being installed on a computer that does have any .NET framework or a .NET framework prior to 2.0 Service Pack 1, see "Systems without .NET 2.0 SP1 or higher" on page 6 for an important installation warning.

Install Phoenix:

There are two ways to start the Phoenix installation process, depending on which delivery method was used to acquire Phoenix.

1. Extract the ZIP file that contains the installation files.
2. Double-click `Setup.exe` to run the Phoenix Installation wizard.

Vista only: Select **Allow** in the **User Account Control** dialog.

OR

1. Insert the Phoenix CD into the computer's CD or DVD drive.
2. If the Phoenix Installation Wizard does not start automatically:
   - Double-click the **My Computer** icon on the desktop or select **My Computer** in the Start menu.
   - Open the Phoenix CD to display its contents.
   - Double-click `Setup.exe` to run the Phoenix Installation wizard.

Vista only: Select **Allow** in the **User Account Control** dialog.

`Setup.exe` detects the operating system and starts the appropriate executable.

Systems without .NET 2.0 SP1 or higher

A forced reboot might occur during the installation process if .NET 2.0 Service Pack 1 is not installed. The reboot occurs before the Phoenix Setup wizard is started.

This primarily occurs on computers running Windows 2000 and XP that do not have any .NET framework components installed.

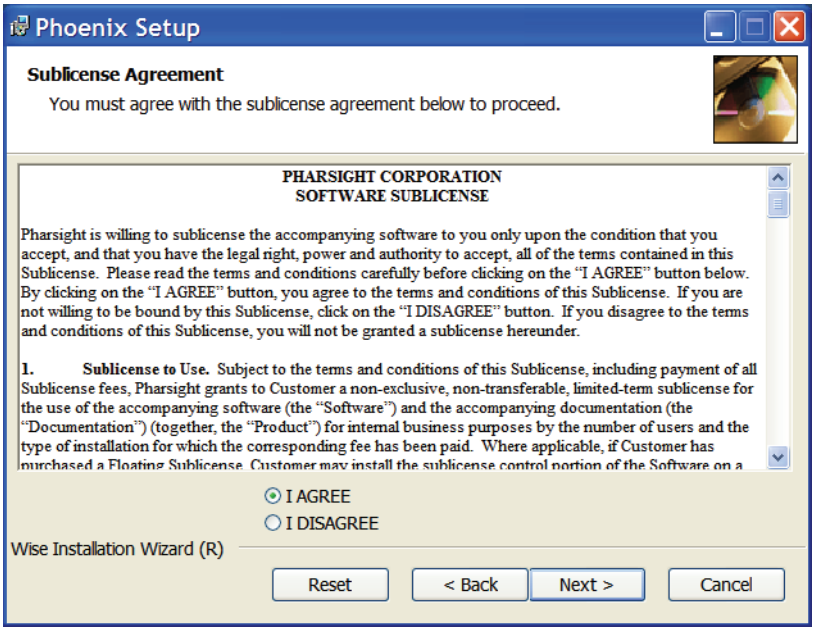
If the computer reboots, start the installation process again by double-clicking `Setup.exe` after the operating system restarts.

Continue the installation:

1. The **Phoenix Setup** wizard is started.

Phoenix Setup
Welcome to the Phoenix Installation Wizard
It is strongly recommended that you exit all Windows programs before running this setup program.
Click Cancel to quit the setup program, then close any programs you have running. Click Next to continue the inst...
WARNING: This program is protected by copyright law and international treaties.
Unauthorized reproduction or distribution of this program, or any portion of it, may result in severe civil and criminal penalties, and will be prosecuted to the maximum extent possible under law.
< Back
Next >
Cancel

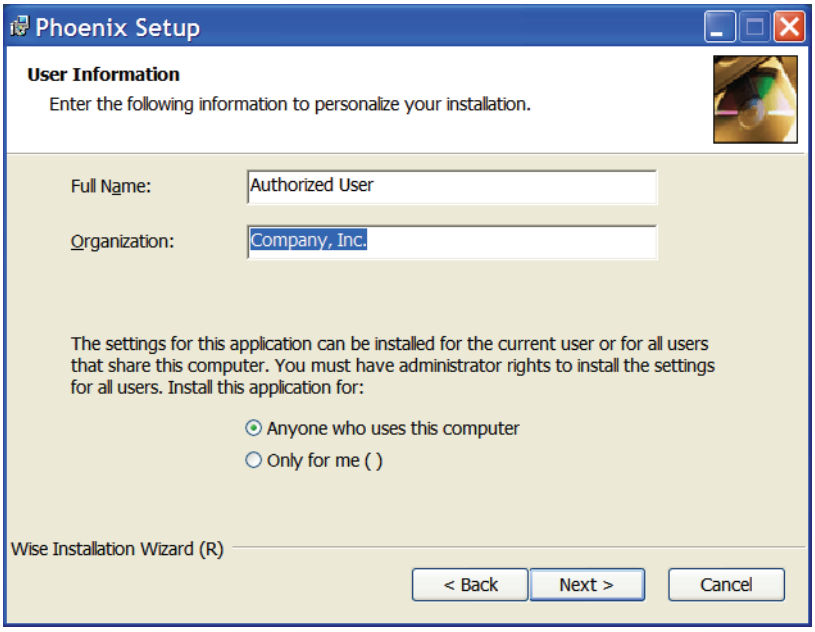
2. Click **Next**. The **Sublicense Agreement** screen is displayed.


Phoenix Setup
Sublicense Agreement
You must agree with the sublicense agreement below to proceed.
PHARSIGHT CORPORATION
SOFTWARE SUBLICENSE
Pharsight is willing to sublicense the accompanying software to you only upon the condition that you accept, and that you have the legal right, power and authority to accept, all of the terms contained in this Sublicense. Please read the terms and conditions carefully before clicking on the "I AGREE" button below. By clicking on the "I AGREE" button, you agree to the terms and conditions of this Sublicense. If you are not willing to be bound by this Sublicense, click on the "I DISAGREE" button. If you disagree to the terms and conditions of this Sublicense, you will not be granted a sublicense hereunder.
1. Sublicense to Use. Subject to the terms and conditions of this Sublicense, including payment of all Sublicense fees, Pharsight grants to Customer a non-exclusive, non-transferable, limited-term sublicense for the use of the accompanying software (the "Software") and the accompanying documentation (the "Documentation") (together, the "Product") for internal business purposes by the number of users and the type of installation for which the corresponding fee has been paid. Where applicable, if Customer has
I AGREE
I DISAGREE
Wise Installation Wizard (R)
Reset
< Back
Next >
Cancel

3. Read the license agreement. To accept its terms and proceed with the installation, select the **I AGREE** option button and click **Next**.

Note: If there are any questions about the agreement, then contact Pharsight's sales department at sales@pharsight.com.

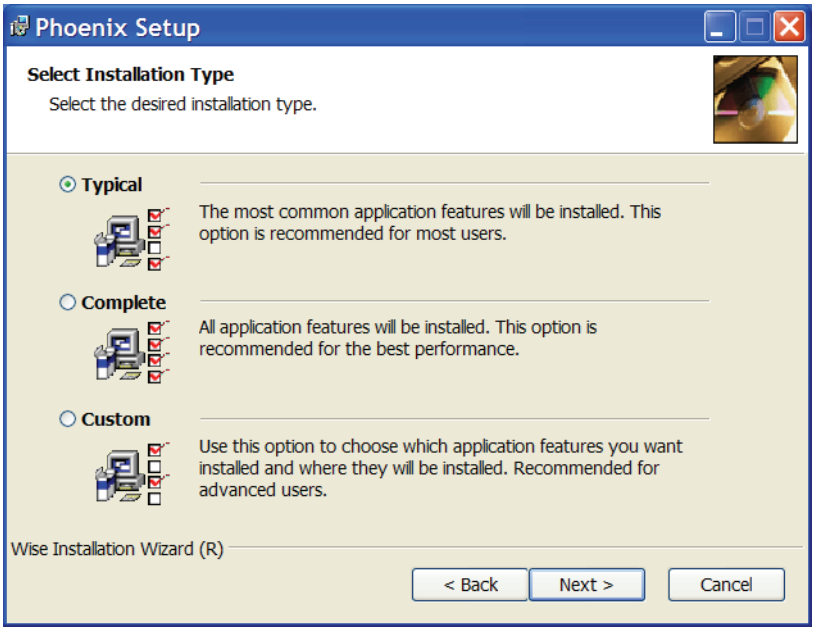
The **User Information** screen is displayed.


Phoenix Setup
User Information
Enter the following information to personalize your installation.
Full Name:
Authorized User
Organization:
Company, Inc.
The settings for this application can be installed for the current user or for all users that share this computer. You must have administrator rights to install the settings for all users. Install this application for:
Anyone who uses this computer
Only for me ( )
Wise Installation Wizard (R)
< Back
Next >
Cancel

4. Enter the appropriate user information and click **Next**.
5. The **Destination Folder** screen is displayed. Accept the default installation directory or choose a directory in which to install Phoenix. Click **Next**.

Vista only: If Phoenix is installed on a machine running Windows Vista 64 bit, then Phoenix is installed in the default directory for 32 bit applications.

The **Select Installation Type** screen is displayed.


Phoenix Setup
Select Installation Type
Select the desired installation type.
Typical
The most common application features will be installed. This option is recommended for most users.
Complete
All application features will be installed. This option is recommended for the best performance.
Custom
Use this option to choose which application features you want installed and where they will be installed. Recommended for advanced users.
Wise Installation Wizard (R)
< Back
Next >
Cancel

6. Select an installation type and click **Next**.

   » **Typical** is the default installation type. MPICH2 is not installed when Typical is selected.

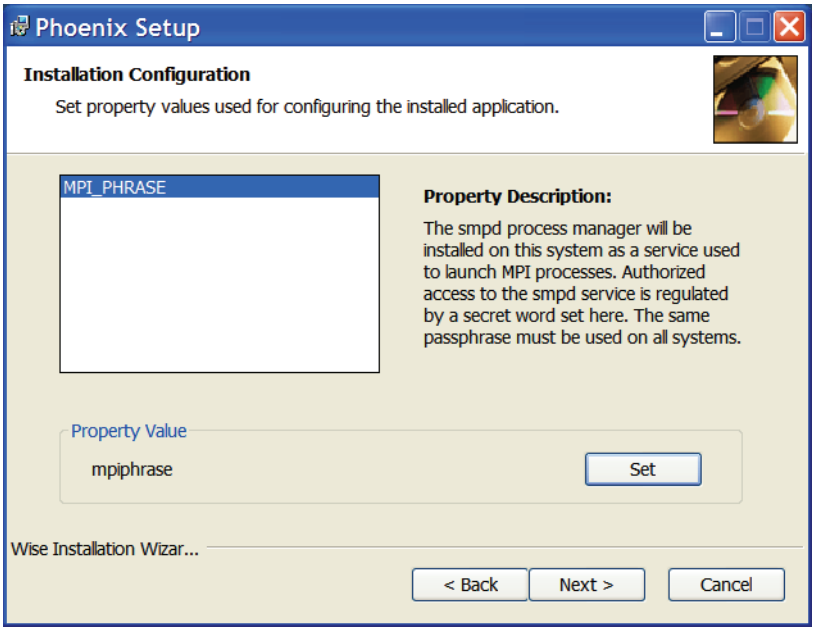
   – If Typical is selected, the Ready to Install the Application screen is displayed.

   » **Complete** installs the MPICH2 software for multiple- CPU and CPU core processing.

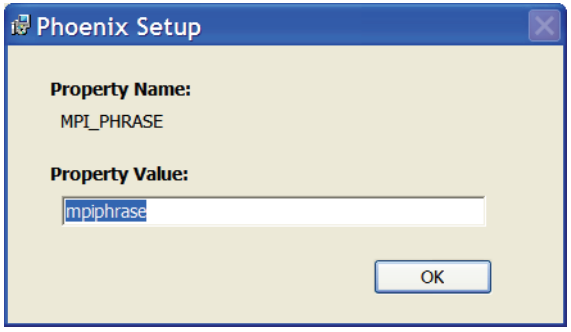
   – If Complete is selected, the MPI passphrase dialog is displayed.

   » **Custom** allows users to make additional choices about what is installed.

   – If Custom is selected, the Select Features dialog is displayed.


Phoenix Setup
Installation Configuration
Set property values used for configuring the installed application.
MPI_PHRASE
Property Description:
The smpd process manager will be installed on this system as a service used to launch MPI processes. Authorized access to the smpd service is regulated by a secret word set here. The same passphrase must be used on all systems.
Property Value
mpiphrase
Set
Wise Installation Wizar...
< Back
Next >
Cancel

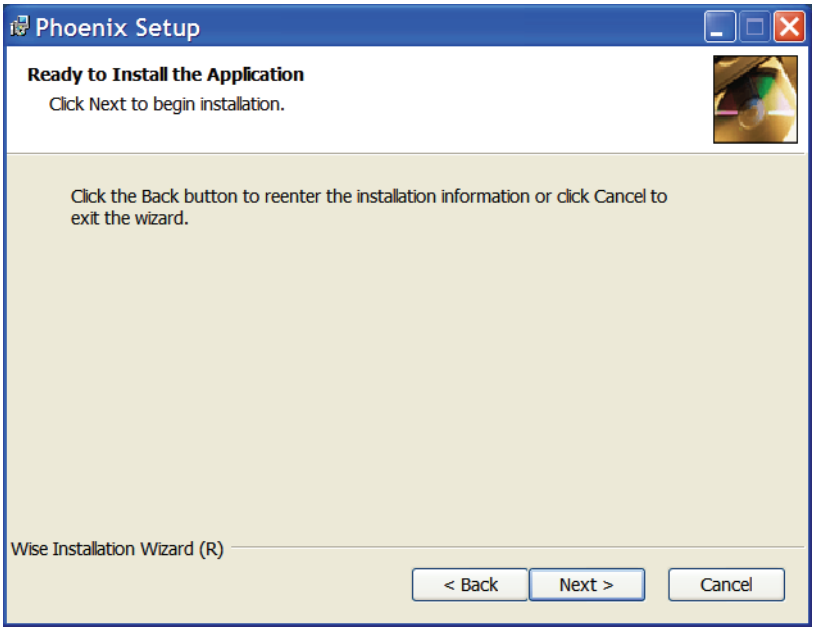
- To change the passphrase from the default, click the **Set** button.
- In the Property Value field, enter a new passphrase and click **OK** to close the dialog.



- Click **Next** to continue the installation.

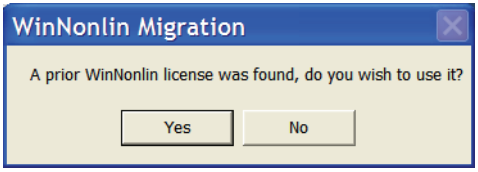
  The **Ready to Install the Application** screen is displayed.

Ready to Install the Application screen


Phoenix Setup
Ready to Install the Application
Click Next to begin installation.
Click the Back button to reenter the installation information or click Cancel to exit the wizard.
Wise Installation Wizard (R)
< Back
Next >
Cancel

7. Use the **Back** button to return to the previous screens to make any changes to the installation.
8. Click **Next** to continue the installation process.

   If a WinNonlin 5.2.1 license is already installed, the Phoenix installation process asks whether or not to use it.



9. Click **Yes** to use the WinNonlin license, or **No** to use a new license.

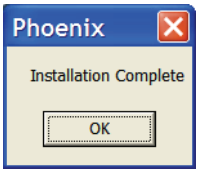
CAUTION: Only click Yes if the WinNonlin license is current.

» For descriptions of the Phoenix plug-ins and features that different WinNonlin licenses activate, see "WinNonlin 5.2.1 license holders" on page 24.

» For a description of where the WinNonlin license file is placed when users select to add it, see "Adding a WinNonlin 5.2.1 license during installation" on page 14.

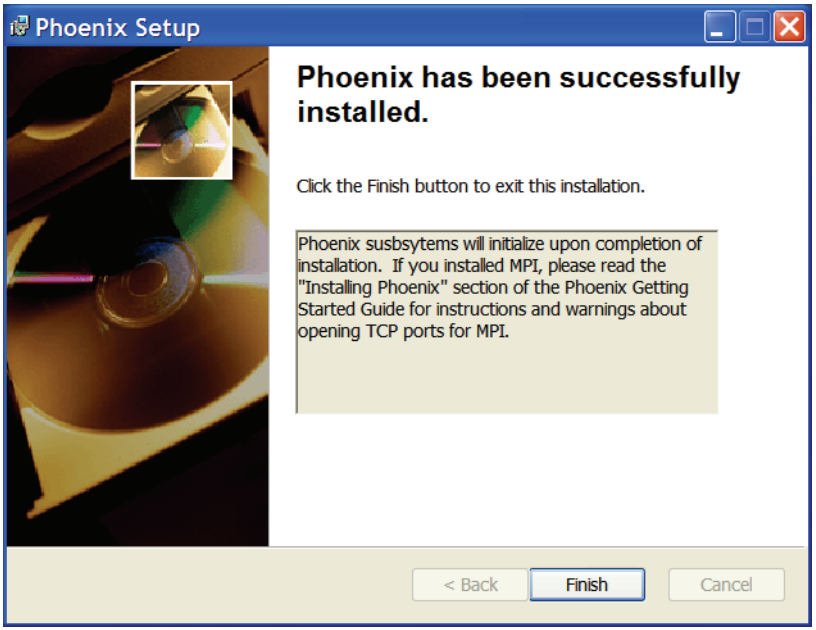
If they are not already installed, the LegacyWNL components and Microsoft Visual C++ 2005 Redistributable are installed.

The installation finishes and the following screen is displayed:



10. Click the **OK** button to exit the Phoenix installation wizard

The Phoenix has been successfully installed screen is displayed.


Phoenix Setup
Phoenix has been successfully installed.
Click the Finish button to exit this installation.
Phoenix susbsytems will initialize upon completion of installation. If you installed MPI, please read the "Installing Phoenix" section of the Phoenix Getting Started Guide for instructions and warnings about opening TCP ports for MPI.
< Back
Finish
Cancel

11. Click **Finish** to finish the installation.

» Users are prompted to restart their computers.

» The Phoenix installation process is finished.

» If the **Complete** installation type was selected, then users need to open TCP ports on their computer to use the MPICH2 software.

– See "Opening TCP ports for MPICH2" on page 16 for instructions on opening TCP ports.

Windows Vista installation

The Vista installation process is similar to the XP installation process with the following exceptions:

» .NET Framework 2.0 Service Pack 1 must be installed before Phoenix can be used.

» By default, Windows Vista comes with the .NET 3.0 framework already installed. .NET 3.0 includes the .NET Framework 2.0 Service Pack 1 components necessary to run Phoenix WinNonlin.

» If the .NET Framework 2.0 Service Pack 1 is not already installed or some of its components are missing, it can be downloaded from the Windows Update Web site.

Note: Vista users must use Windows Update to get .NET 2 SP 1.

Windows 2003 Citrix Server installation

If Phoenix is installed on Windows 2003 Citrix Server, then the computer must be rebooted after the installation in order for the operating system to update the system variables path statement to include the MinGW compiler. This step is necessary to use the Phoenix Model object.

Adding a WinNonlin 5.2.1 license during installation

By default, the WinNonlin license file `lservrc` is located in `C:\Program Files\Pharsight\WinNonlin`. If a user chooses to add the WinNonlin license during the installation process, it is copied to the default Phoenix installation directory `C:\Program Files\Pharsight\Phoenix\application\Services\Licensing` in both Windows XP and Vista.

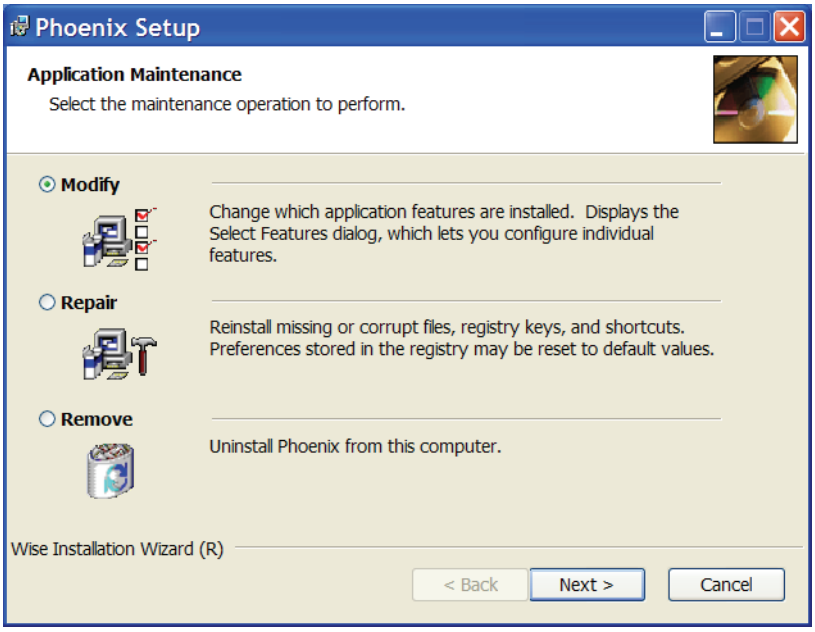
Modifying, updating, or removing a Phoenix installation

If Phoenix is already installed, then users can double-click the `Setup.exe` or the `Setup.msi` file to update or modify a Phoenix installation.

- Double-click the `Setup.exe` or the `Setup.msi` file.

  The Phoenix Application Maintenance screen is displayed.

Application Maintenance screen


Phoenix Setup
Application Maintenance
Select the maintenance operation to perform.
Modify
Change which application features are installed. Displays the Select Features dialog, which lets you configure individual features.
Repair
Reinstall missing or corrupt files, registry keys, and shortcuts. Preferences stored in the registry may be reset to default values.
Remove
Uninstall Phoenix from this computer.
Wise Installation Wizard (R)
< Back
Next >
Cancel

- Select a maintenance operation and click **Next**.

» **Modify** is the default selection type. Modify allows users to make additional choices about what is installed.

– If Modify is selected, the Select Features dialog is displayed.

» **Repair** reinstalls parts of Phoenix that need to be corrected or updated

– If Repair is selected, the Ready to Repair the Application screen is displayed.

» **Remove** uninstalls Phoenix.

– If **Remove** is selected, the Phoenix Uninstall screen is displayed.

If Repair is selected, Phoenix is re-installed based on the user selections made when Phoenix was originally installed.

Configuring Phoenix for international use

When Phoenix is installed on systems that do not use the United States region, then some regional display information must be changed before Phoenix can be used.

CAUTION: If the settings are not changed then Phoenix cannot correctly run projects that are created in the English (United States) region.

- In the Control Panel, open the **Regional and Language Options** dialog.
- In the Regional and Language Options dialog, select **English (United States)** as the region.

  If the region information cannot be changed, then users must set the decimal symbol to a period (**.**) for numbers and currency, and the list separator symbol to a comma (**,**).
- Click the **Customize** button. The Customize Regional Options dialog is displayed.
- In the **Decimal symbol** menu, change the decimal symbol to a period (**.**).
- In the **List separator** menu, select a comma (**,**).
- Select the **Currency** tab.
- In the **Decimal symbol** menu, change the decimal symbol to a period (**.**).
- Click **OK** and then **Apply** to save the changes.

Opening TCP ports for MPICH2

MPICH2 is an implementation of the **M**essage **P**assing **I**nterface (MPI) standard, which allows users to process Phoenix models using multiple CPUs or CPUs with multiple cores.

Note: Phoenix's MPI feature can be used in a networked computing environment, where multiple computer are used to run Phoenix models. Please contact your IT support personnel for help with opening ports in a networked computing environment.

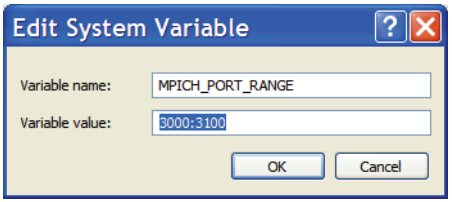
MPICH2 must use certain TCP ports. If TCP ports are not opened for MPICH2, and the computer uses a software firewall, then the firewall might display alerts each time MPICH2 is run.

The multiple alerts are displayed because the executable that uses MPICH2 is compiled dynamically with each execution, so adding an exemption in a firewall for MPICH2 might work only temporarily.

» Users can restrict MPICH2 to use a range of ports, and open those ports in a firewall to avoid the multiple warnings.

» Users can also set a system environment variable named MPICH_PORT_RANGE with a value of <port range start>:<port range end>. This restricts MPICH2 to only use the given port range.

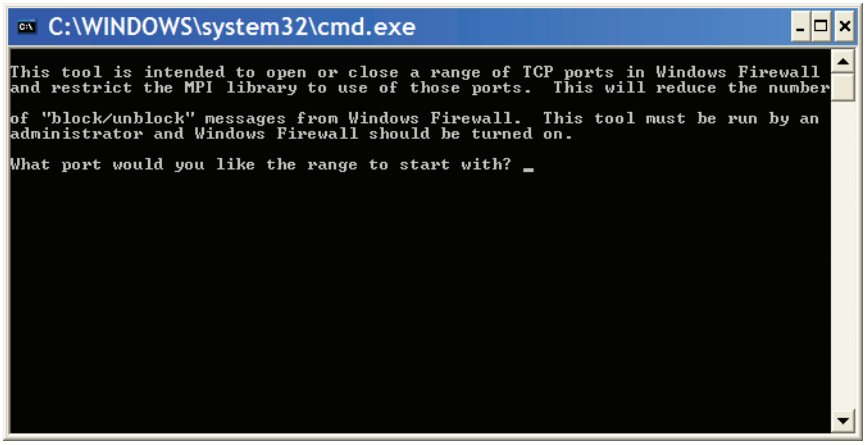
» For example, use MPICH_PORT_RANGE=3000:3100 to restrict to the range to 3000-3100.



Pharsight provides a batch file called `mpiPortTool.bat` that allows users to automatically open and close ports for MPICH2 in Windows Firewall. Users must be logged in as an administrator for the batch file to work correctly.

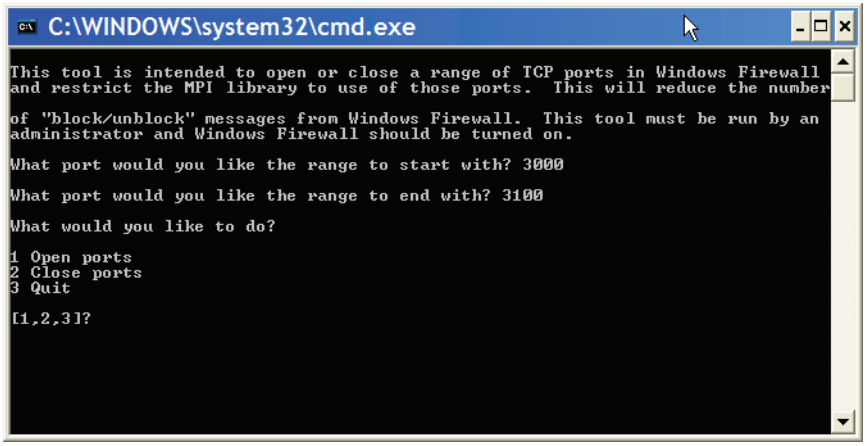
The default location of the batch file is `C:\Program Files\Pharsight\MPICH2\tools\mpiPortTool.bat`. The batch file is installed only if MPICH2 is installed.

- Double-click `mpiPortTool.bat`. A command prompt is opened that asks users what port range to use.


C:\WINDOWS\system32\cmd.exe
This tool is intended to open or close a range of TCP ports in Windows Firewall and restrict the MPI library to use of those ports. This will reduce the number
of "block/unblock" messages from Windows Firewall. This tool must be run by an administrator and Windows Firewall should be turned on.
What port would you like the range to start with? _

- At the prompt, enter a beginning port number, such as 3000. Press ENTER.
- Enter an ending port number such as 3100. Press ENTER.

The batch file then presents three options that allow users to open ports, close ports, or quit.


C:\WINDOWS\system32\cmd.exe
This tool is intended to open or close a range of TCP ports in Windows Firewall and restrict the MPI library to use of those ports. This will reduce the number of "block/unblock" messages from Windows Firewall. This tool must be run by an administrator and Windows Firewall should be turned on.
What port would you like the range to start with? 3000
What port would you like the range to end with? 3100
What would you like to do?
1 Open ports
2 Close ports
3 Quit
[1,2,3]?

- Press 1 to add the port numbers to Windows Firewall.
  - A second command prompt is opened and adds the selected port range.
  - The batch file also creates a system environment variable that includes the port numbers.

Chapter 2

Licensing

Installation and renewal of Phoenix software licenses

The chapter contains the following topics:

» "Phoenix Licensing Service" on page 19
  – "License key code types" on page 20
  – "Plug-in licenses" on page 21
  – "Product and authorization codes" on page 20
  – "WinNonlin 5.2.1 license holders" on page 24
» "License Activation" on page 25
» "Setting up a license server" on page 30
» "License Management" on page 31
» "License Server Management" on page 33

Phoenix Licensing Service

The Phoenix Licensing Service is the system Phoenix uses to manage user licenses. When a user starts Phoenix for the first time the Licensing Service is the first Phoenix service that is initialized, and the No Framework License message is displayed if no license is detected. The Licensing Service is integrated into the Phoenix Preferences menu, which can be accessed by selecting **Preferences** in the **Edit** menu.

Users have several options to install or acquire a license. Users can activate their copy of Phoenix by using online and offline activation, or users can connect to a license server to acquire a license for online or offline use.

License key code types

Phoenix requires the installation of a license key code. There are three types of license key codes:

1. Node - a license key code that activates the software on the machine on which it is installed. The license agreement restricts installation of the software and license to a single personal computer (PC) per node license.
2. Floating - a license key code that enables multiple PCs in a networked environment to run Phoenix using a shared pool of software licenses. The number of simultaneous users is limited to the total number of licenses on the license server.
3. Commuter - a floating license key code that is retrieved from a network. Commuter licenses give users temporary offline authorization to use Phoenix while away from the network where their floating license server resides.

   Commuter licenses can be used for a specified period of time and are subject to a hold time during which they cannot be checked out by another user. This protects users who need to make changes to a Phoenix project after they close Phoenix from immediately losing their license key to another user on the network.

   Customers must work with Pharsight Sales and the Licensing Administrator to determine how many of their floating licenses should contain the commuter feature and the length of time that commuter enabled licenses are valid after they have been checked out from the license server. The time-out period can not be altered after the license has been installed.

Note: The commuter license option is only available if the Sentinel™ RMS 8.x license server is used with Phoenix.

For more on using a license server with Phoenix, see "Setting up a license server" on page 30.

Product and authorization codes

A product code and an authorization code are included with each license or set of licenses purchased. The primary delivery system for acquiring the Phoenix application is downloading the installation files from a Pharsight server. Pharsight's download and support page is located at http://www.pharsight.com/support/support_home.php.

When Phoenix is purchased, customers are sent an email with the five things necessary to use Phoenix:

- The application download link.
- The license server download link.
- The authorization code.
- The product code.
- The license code generation Web site link.

A CD can be ordered for users who want a physical medium. To purchase a CD, contact Pharsight's sales department at:

E-mail:	sales@pharsight.com
Telephone:	1-888-708-7444 (US only)
	+1-919-852-4685
Fax:	+1-650-314-3811

For mail shipments, the product and authorization codes are located on the packing slip shipped with the software, and on the product's CD jewel case.

Please include the product code in all correspondence with Pharsight Corporation about the product and its license, including license renewals, software updates, and product upgrades.

Plug-in licenses

Phoenix uses a plug-in architecture to create system functions. Phoenix allows users to enable, disable, configure, and create plug-ins. All Phoenix framework functions and plug-ins require a license before they can be used.

The following table shows which framework features and plug-ins are enabled by the different license types. Some features and plug-ins require customers to purchase one or more licenses before they can be used. The features and plug-ins that are enabled by each license are listed in the following table.

Table 2-1. Phoenix plug-in license matrix

Feature/Plug-in	Phoenix Connect	Phoenix WinNonlin	Phoenix NLME
Data objects			
Append Worksheets	**X**	**X**	**X**

Table 2-1. Phoenix plug-in license matrix

Feature/Plug-in	Phoenix Connect	Phoenix WinNonlin	Phoenix NLME
BQL	X	X	X
Column Properties	X	X	X
Column Transformation	X	X	X
Crossproduct Worksheets	X	X	X
Filter Worksheet	X	X	X
Join Worksheets	X	X	X
Merge Worksheets	X	X	X
Pivot Worksheet	X	X	X
Rank Worksheet	X	X	X
Split Worksheet	X	X	X
Stacker	X	X	X
Plotting objects			
Bar Plot	X	X	X
Column Plot	X	X	X
Box Plot	X	X	X
Histogram	X	X	X
XY Plot	X	X	X
QQ Plot	X	X	X
Scatter Plot Matrix	X	X	X
NCA and Toolbox objects			
NCA		X	
Bioequivalence		X	
Crossover		X	
Deconvolution		X	
Descriptive Stats		X	X
Linear Mixed Effects		X	
NonParametric		X	
SemiCompartmental		X	
WNL5 Classic Modeling objects			

Table 2-1. Phoenix plug-in license matrix

Feature/Plug-in	Phoenix Connect	Phoenix WinNonlin	Phoenix NLME
Indirect Response Model		X	
Linear Model		X	
Michaelis-Menten Model		X	
PD Model		X	
PK Model		X	
PK/PD Model		X	
WNL5 ASCII Format model		X	
WNL-Phoenix Modeling object			
Phoenix Model (individual)		X	X
Phoenix Model (population)			X
Phoenix Model Comparer			X
Reporting object			
Table		X	X
NONMEM object			
NONMEM Shell	X		X
NONMEM Comparer	X		X
SAS object			
SAS Shell	X		
SigmaPlot object			
SigmaPlot Shell	X		
S-PLUS object			
S-PLUS Dataframe Import	X		
S-PLUS Script	X		
S-PLUS Worksheet Export	X		
R Script object			
R script	X		X
PKS Connectivity	X		

Table 2-1. Phoenix plug-in license matrix

Feature/Plug-in	Phoenix Connect	Phoenix WinNonlin	Phoenix NLME
CDISC import and export	X		
ODBC Connectivity	X		
Word Export	X	X	X
Edit in Excel	X	X	X
Plug-in APIs	X	X	X
Phoenix Framework	X	X	X

WinNonlin 5.2.1 license holders

Users who have WinNonlin 5.2.1 licenses can use Phoenix with no intervention from Pharsight as long as the WinNonlin license is current.

During the installation process Phoenix looks for an existing WinNonlin license. If it finds one, it gives the user the option of using it. If a user chooses to use the existing license, a copy of the license file, `lservrc`, is written to the default Phoenix license file location at `C:\Program Files\Pharsight\Phoenix\application\Services\Licensing` in Windows XP and Vista.

Users can also copy and paste the lservrc file from the WinNonlin installation directory (`C:\Program Files\Pharsight\WinNonlin` by default) to the Phoenix licensing service directory in Windows XP (`C:\Program Files\Pharsight\Phoenix\application\Services\Licensing` by default) or Vista (`C:\Program Files\Pharsight\Phoenix\application\Services\Licensing` by default).

» A WinNonlin 5.2.1 Professional license is equivalent to the Phoenix WinNonlin license.

» A WinNonlin 5.2.1 Enterprise license is equivalent to the combination of the Phoenix WinNonlin and Phoenix Connect licenses.

WinNonlin 5.2.1 floating license servers

WinNonlin license servers are not detected during the installation process on Windows Vista. The license server IP address must be entered manually in the License Server Management screen in the Preferences dialog.

License Activation

Phoenix must be installed before the license key code can be installed. See "Installing Phoenix" on page 5.

When using Nodes, there are three types of Phoenix license activations: online, offline, and manual.

Users can also visit the license code generation Web site and receive their license code. The Web site link is emailed when Phoenix is purchased.

Note: If a user enables PKS connectivity by activating a Phoenix Connect 1.0 license, Phoenix must be restarted to enable PKS functions.

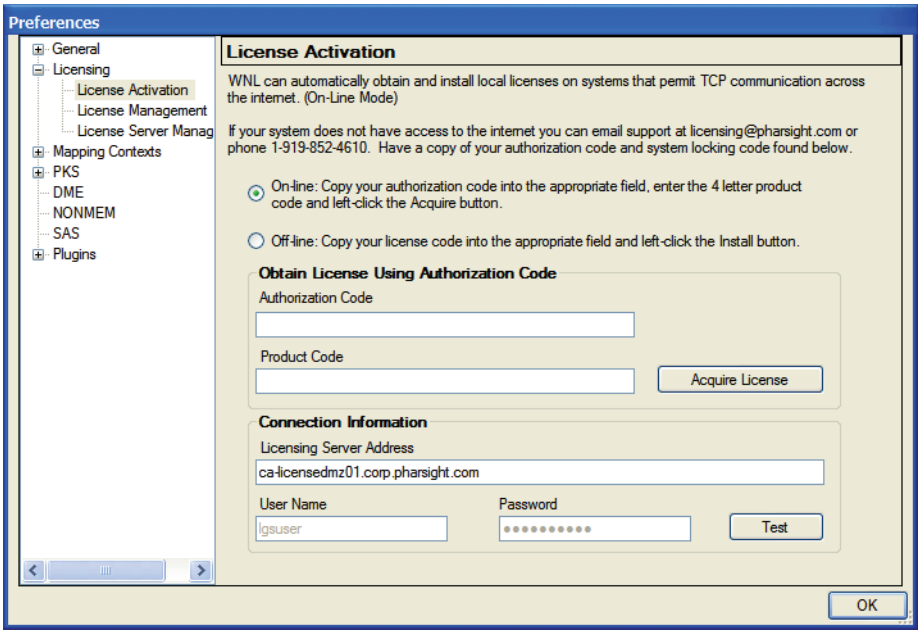
Active a license:

1. In the **Edit** menu select **Preferences**.
2. In the Preferences dialog, click the (+) sign beside **Licensing** to expand the Licensing menu.
3. Select **License Activation**.
4. In the License Activation screen, select either On-line activation: or Off-line activation using a Pharsight Web site:.
   - » Use the On-line method if you have internet access and have the authorization and product codes that are supplied with your copy of Phoenix.
   - » Use the Off-line method if you do not have internet access but you do have the license code that is supplied with your copy of Phoenix.
   - » Both types of license activation require internet access. If license activation over the internet is not possible, see "Manual activation:" on page 30.

On-line activation:

On-line activation allows users to activate Phoenix by connecting to Pharsight's licensing server from within Phoenix.

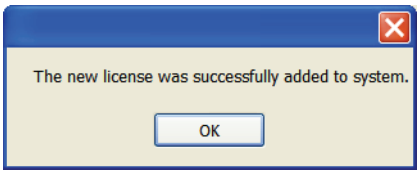
Online license activation


Preferences
General
Licensing
License Activation
License Management
License Server Manag
Mapping Contexts
PKS
DME
NONMEM
SAS
Plugins
License Activation
WNL can automatically obtain and install local licenses on systems that permit TCP communication across the internet. (On-Line Mode)
If your system does not have access to the internet you can email support at licensing@pharsight.com or phone 1-919-852-4610. Have a copy of your authorization code and system locking code found below.
On-line: Copy your authorization code into the appropriate field, enter the 4 letter product code and left-click the Acquire button.
Off-line: Copy your license code into the appropriate field and left-click the Install button.
Obtain License Using Authorization Code
Authorization Code
Product Code
Acquire License
Connection Information
Licensing Server Address
ca-licensedmz01.corp.pharsight.com
User Name
lgsuser
Password
Test
OK

1. Select the **On-line** option button.
2. Enter the authorization code in the **Authorization Code** field.

   The authorization code is contained in an email attachment named `AuthorizationCode.txt` that is sent by Pharsight's License Administrator. Users can copy and paste the code.
3. Enter the product code in the **Product Code** field. For example, PHX_WNL for Phoenix WinNonlin.
4. Click the **Acquire License** button.

Phoenix displays a message stating the license was successfully added.



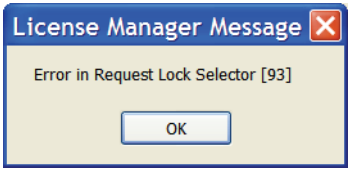
A license file named `lservrc` is written to different locations depending on the operating system.

» In Windows XP, the default location `C:\Program Files\Pharsight\Phoenix\application\Services\Licensing`.

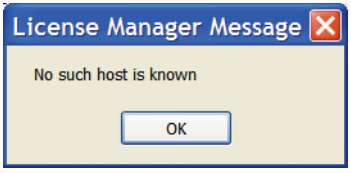
» In Windows Vista, the default location `C:\Users\username>\AppData\Local\VirtualStore\Program Files\Pharsight\Phoenix\application\Services\Licensing`.

If the license was not added, Phoenix displays different error messages depending on the problem.

If the authorization code was not entered correctly, Phoenix displays the following message:



If the network connection cannot be established, Phoenix displays the following message:



The license server settings are static and cannot be changed.

- Click the **Test** button to make sure the server connection can be established.

Note: If Windows displays the error message 10019, Cannot Connect to Server, then your network environment might be blocking Phoenix from accessing Pharsight's licensing server. This can be due to port 5094 being closed. Request that your IT department open port 5094, or go to "Manual activation:" on page 30.

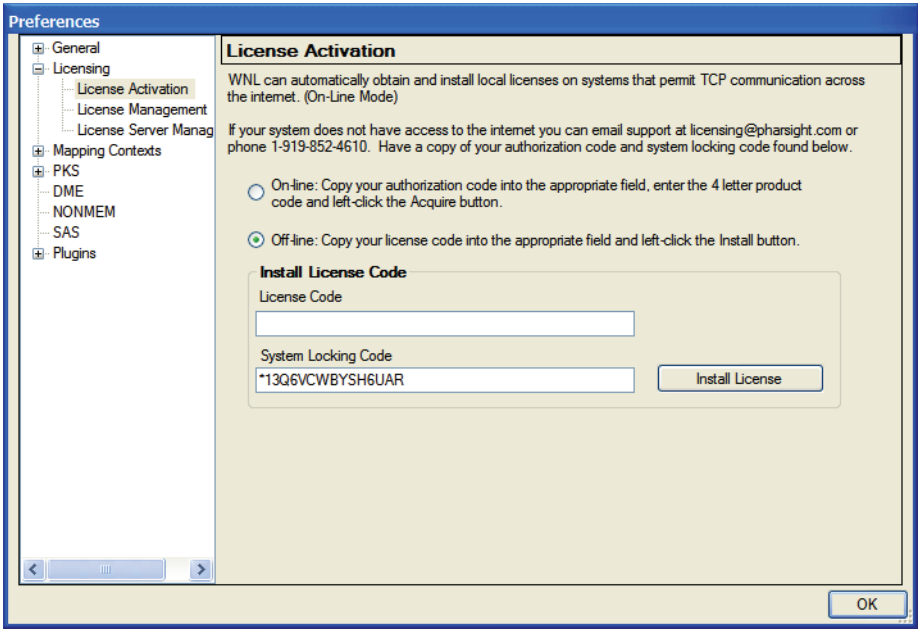
Off-line activation using a Pharsight Web site:

Off-line activation allows users to activate Phoenix by installing a license code.

- To confirm the acquisition and installation of the license, select **License Management** in the **Licensing** menu.

The purchased license is displayed in the Licenses list.

Offline license activation


Preferences
General
Licensing
License Activation
License Management
License Server Manag
Mapping Contexts
PKS
DME
NONMEM
SAS
Plugins
License Activation
WNL can automatically obtain and install local licenses on systems that permit TCP communication across the internet. (On-Line Mode)
If your system does not have access to the internet you can email support at licensing@pharsight.com or phone 1-919-852-4610. Have a copy of your authorization code and system locking code found below.
On-line: Copy your authorization code into the appropriate field, enter the 4 letter product code and left-click the Acquire button.
Off-line: Copy your license code into the appropriate field and left-click the Install button.
Install License Code
License Code
System Locking Code
*13Q6VCWBYSH6UAR
Install License
OK

1. Select the **Off-line** option button.
2. Go to the following Web site: http://licensing.pharsight.com/requestlicense/default.aspx.
3. Enter the authorization code you received from Pharsight into the **Authorization Code** field.
4. Enter the system Locking Code from the License Activation panel in the Preferences menu in the **Locking Code** field.
5. Click the **Request License** button and the License code is displayed in the License Code field.
6. Save the license code to a text file by clicking the **Save License** button.
7. Copy the file to the computer on which Phoenix is installed.

The license file named `lservrc` must be written to different locations depending on the operating system.

» In Windows XP, the default location `C:\Program Files\Pharsight\Phoenix\application\Services\Licensing`.

» In Windows Vista, the default location `C:\Users\username>\AppData\Local\VirtualStore\Program Files\Pharsight\Phoenix\application\Services\Licensing`.

8. In the License Code field, enter the License Code from the text file and click the **Install License** button.

- To confirm license installation, select **License Management** in the preferences dialog.

  The purchased license is displayed in the Licenses list.

  If the license code was not entered correctly, Phoenix displays the following message:

License Manager Message
The license code entered is invalid.
Please make sure you are not entering an authorization code instead of a license code.
OK

Manual activation:

If you need to manually obtain a license code, then contact Pharsight by phone at +1-919-852-4610 or by email at licensing@pharsight.com.

Users need their authorization and system locking codes to obtain a license over the phone or by email.

When the license code is obtained follow the instructions under "Off-line activation using a Pharsight Web site:" on page 28 to install the license and activate Phoenix.

Setting up a license server

The Sentinel RMS license server must be installed before the floating and commuter licenses can be used on a client machine. The license server only needs to be installed on one computer, but the latest version of the Sentinel RMS license server supports redundant license servers.

Note: Contact Pharsight customer support (support@pharsight.com) for suggestions on how best to deploy a license server for Phoenix.

The license server provided for Phoenix is Sentinel RMS server 8.x. It is available for download when Phoenix is purchased. The download link for the license server is included in the email sent to new Phoenix customers.

It is also located on the Phoenix installation CD in the directory `Tools\Sentinel RMS License Manager Installer`.

Sentinel RMS server 8.x is backwards compatible with WinNonlin 5.2.1, and can be used to provide floating licenses for WinNonlin 5.2.1, Phoenix WinNonlin 6.0, and Phoenix Connect 1.0.

The license server provided with WinNonlin 5.2.1 is based on Sentinel RMS server 7.

CAUTION: Phoenix can use the older license server, but version 7 DOES NOT support commuter licenses or redundant license servers.

Mass deployment of license configuration files

IT personnel can configure Phoenix on one system and then copy the license configuration files to every Phoenix installation. This allows IT personnel to configure one instance of Phoenix to use a local license server, and then copy the configuration files to every Phoenix installation in the network.

The three license configuration files are:

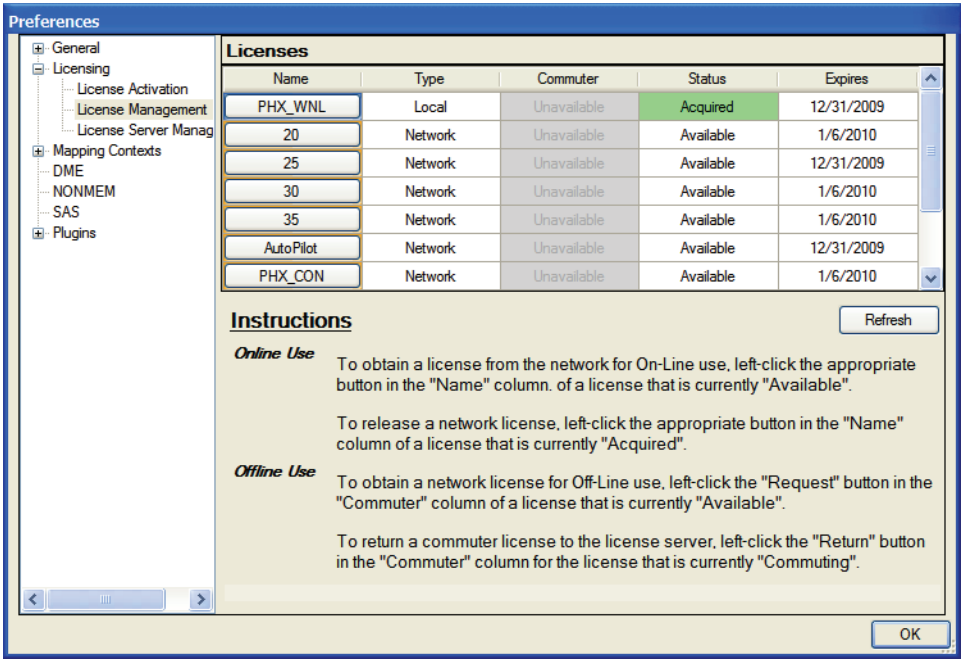
- `licensing.licenses.configuration.binconfig`
- `licensing.server.configuration.binconfig`
- `licensing.service.configuration.binconfig`

By default, the files are located in `C:\Documents and Settings\<username>\Application Data\Pharsight\Phoenix\Configuration` in Windows XP and `C:\Users\<username>\AppData\Roaming\Pharsight\Phoenix\Configuration` in Windows Vista.

License Management

The License Management screen allows users to see which license types are available and acquired, as well as the different plug-ins they allow users to access.

Phoenix license manager



The License Management dialog has five fields:

Table 2-2. License Management fields

Field	Function
Name	Lists the names of available licenses.
Type	Lists whether the license is local (node) or network (floating or commuter).
Commuter	Lists floating licenses that are available to be commuted.
Status	Lists the status (Available, Acquired, etc.) of licenses
Expires	Lists the license expiration date.

Use the License Management dialog:

1. In the **Edit** menu select **Preferences**. The **Preferences** dialog is displayed.
   - Expand items in the Preferences menu tree by clicking the (+) signs.

2. Select **Licensing>License Management** in the Preferences dialog menu tree.

Node licenses

There are no options for node licenses in the License Management screen.

Floating licenses

1. To use a floating license, click a network license name in the **Name** column.

The license status is changed to Acquired.

2. Click the license name again to return the license. The license status is now Available.

Commuter licenses

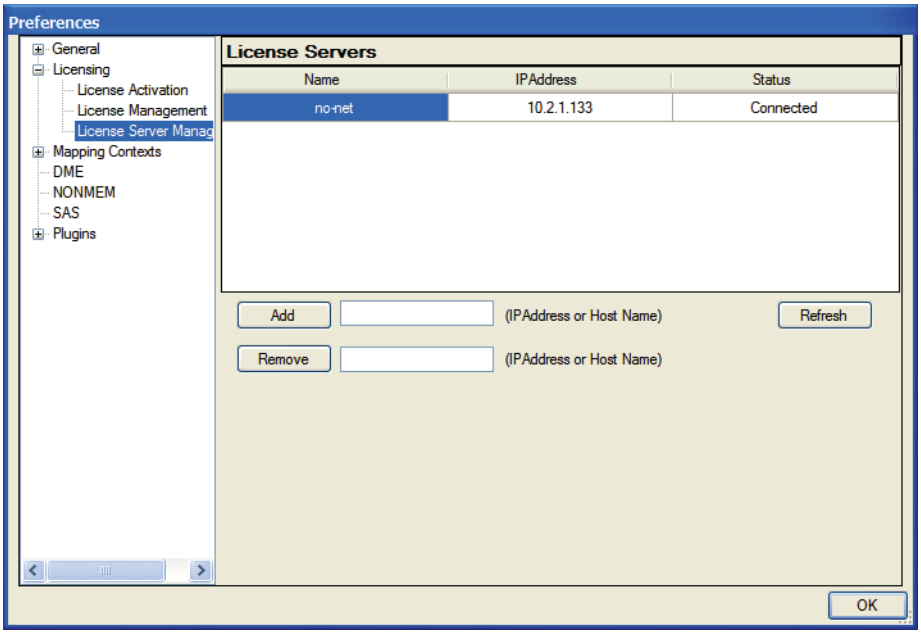
1. If a commuter license is available, click the **Request** Request button in the Commuter column.
2. If the commuter license is acquired, and its status is changed to Commuting.
3. The date the commuter license expires is listed in the Expires column.
4. To return a commuter license, click the **Release** Release button to release the license.
5. Click the **Refresh** Refresh button to update the list of available licenses.

License Server Management

The License Server Management screen allows users to add license server IP addresses to Phoenix. The number of available license servers is determined by the customer. Some versions of Sentinel license servers support redundant license servers.

The License Server Management screen has three fields: Name, IP Address, and Status. The Name field contains the name of the license server, the IP Address field contains the IP address of the license server, and the Status field contains the connection status.

License Server Management screen



Use the License Server Management screen:

1. To add a license server, enter the IP address of the server in the **IP Address or Host Name** field beside the Add button and click the **Add** button.
2. To remove a floating license server, enter the IP address of the server in the **IP Address** field and click the **Remove** button.

   • Click the **Refresh** button to update the list of available license servers.

Chapter 3

Testing the Installation

Confirming proper installation of the main Phoenix functions

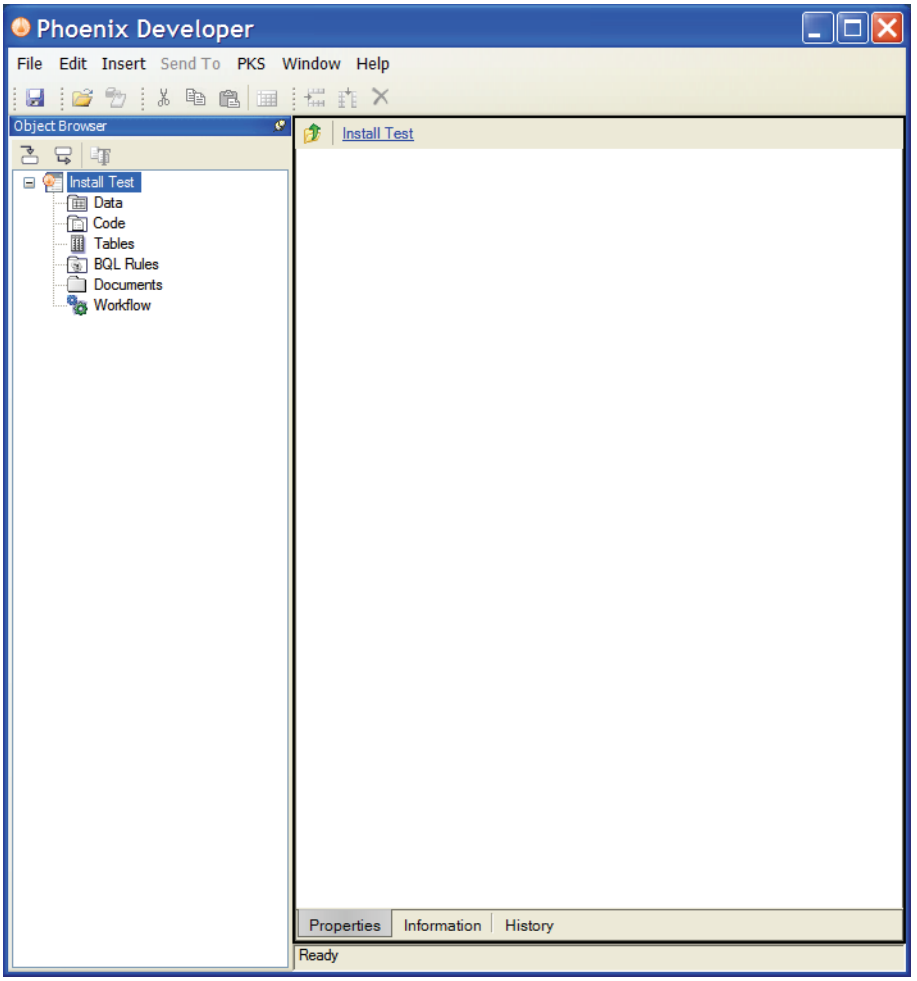
The following instructions test the installation of Phoenix by using a number of the sample files provided with the software. This chapter is not intended as a full validation of the product. It is intended to test for proper installation of major components of the application.

A complete validation kit is available from Pharsight Corporation. Contact the Pharsight sales department for more information. Users interested in a validation kit should send an e-mail to sales@pharsight.com, or phone sales at 1-888-708-7444 (US only) or +1-919-852-4685 (international).

Start Phoenix and create a new project

1. In the Windows **Start** menu, select **All Programs>Pharsight>Phoenix>Phoenix** to start Phoenix.
2. In the **File** menu select **New Project** to create a new project. A new project is created in the Object Browser.
3. Name the new project `Install Test`.

The left panel's default view is the Object Browser, which contains the project, and the other folders and objects that are contained in the project. The right viewing panel's default view is blank, unless one of the project folders or the workflow is selected.



Confirm license installation

The ability to execute different Phoenix plug-ins depends on the license type installed. Use the Preferences dialog to check the installed Phoenix license(s).

1. In the **Edit** menu select **Preferences** to access the **Preferences** dialog.
2. In the Preferences menu tree, select **Licensing>License Management** to access the list of available licenses.
3. Confirm that the purchased license or licenses are listed in the Licenses panel.
4. Click **OK** to exit the Preferences dialog.

Confirm plug-in startup

The Phoenix architecture is based on a series of plug-ins that allow different features to be enabled or disabled. Phoenix initializes these plug-ins when the application starts. The default setting is for all plug-ins to initialize when Phoenix starts. The plug-in initialization is independent of the installed license(s).

1. In the **Edit** menu select **Preferences**. The **Preferences** dialog is displayed.
   - Expand items in the Preferences menu tree by clicking the (+) signs.
2. In the Preferences menu tree, click the (+) sign beside **Plugins** to view the list of available plug-ins.
   » The Plugins menu contains three tabs: **General**, **System**, and **Non-loaded**.
   » Each plug-in has two possible states, **Started** and **Stopped**.
   » All plug-ins are started the first time Phoenix is started.
3. Select the **General**, **System**, and **Non-loaded** tabs to see the review the state of each plug-in type and to confirm they are started.
4. Click **OK** to exit the Preferences dialog.

Import a data set

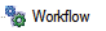
The data set `Bguide1.dat` is used to test key Phoenix functions.

1. In the **File** menu select **Import** or click the **Import** **button**. The **Open File(s)** dialog is displayed.
2. Navigate to the Phoenix examples subdirectory, which by default is located at `C:\Program Files\Pharsight\Phoenix\application\Examples`.
3. In the **Files of type** menu select ASCII Data (`*.csv;*.dat`).
4. Select the file `Bguide1.dat` and click **Open**.

The **Worksheet Import Options** dialog is displayed. The dialog is used to assign options for how the data are imported and presented.

5. Click **Finish**. The data set is added to the project's **Data folder**.
6. View the data set by selecting it in the Data folder. The worksheet is displayed in the **Grid** tab, which is located in the right viewing panel.

Create a plot

1. Select the workflow object  in the Object Browser. In the **Insert** menu select **Plotting>XY Plot**.

   - The XY Plot object can also be added by right-clicking the workflow object and selecting **New>Plotting>XY Plot**. Any object can be added by selecting **New** in the workflow menu.

The **XY Plot** object is added to the workflow in the Object Browser.

» Objects automatically open in the right viewing panel when they are inserted in a workflow.

» Each object's default view is the **Setup** tab, which contains all the steps necessary to set up an object.

2. Map the data set **Bguide1** as the input source for the XY Plot object:

   - Use the pointer to drag the **Bguide1** worksheet from the Data folder to the **XY Data** Mappings panel.

     or

   - In the XY Plot's **XY Data** Mappings panel click the **Select source** button to open the **Select Object** dialog.
   - Click the (+) signs beside **Install Test>Data** to expand the menu tree.
   - Select **Bguide1** and click **Select**.

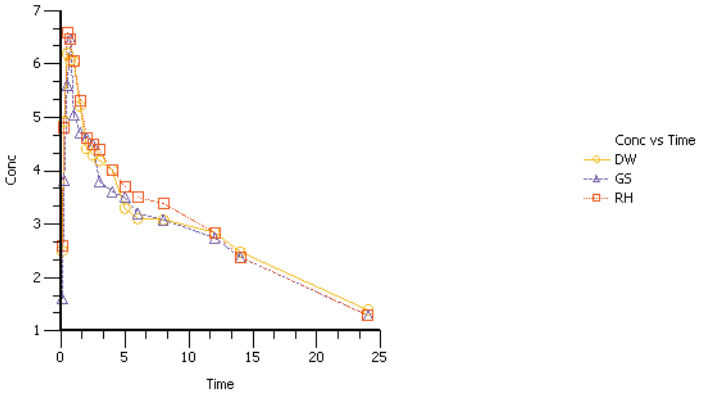
     The Bguide1 data set is mapped to the XY Plot object.

3. Use the option buttons in the **XY Data** Mappings panel to map the data types to the following contexts:

   - Map **Subject** to the Group context.
   - Map **Time** to the X context.
   - Map **Conc** to the Y context.

4. Click the **Execute** button. The Results are displayed on the Results tab.

XY Plot results



- Now use the Bguide1 data set to test the Table object and its summary statistics function.

Create a table

1. Select the workflow object in the Object Browser. In the **Insert** menu select **Reporting>Table**.
   - The Table object can also be added by selecting the workflow in the Object Browser. The workflow Diagram tab is displayed in the right viewing panel.
   - Click the **Table** button in the Object toolbox. The Table object is added to the Diagram tab.
   - Select the Table object in the Object Browser to view the object's Setup tab.

The **Table** object is added to the workflow in the Object Browser.

2. Map the data set **Bguide1** as the input source for the Table object:
   - Use the pointer to drag the **Bguide1** worksheet from the Data folder to the Table object's **Main** Mappings panel.

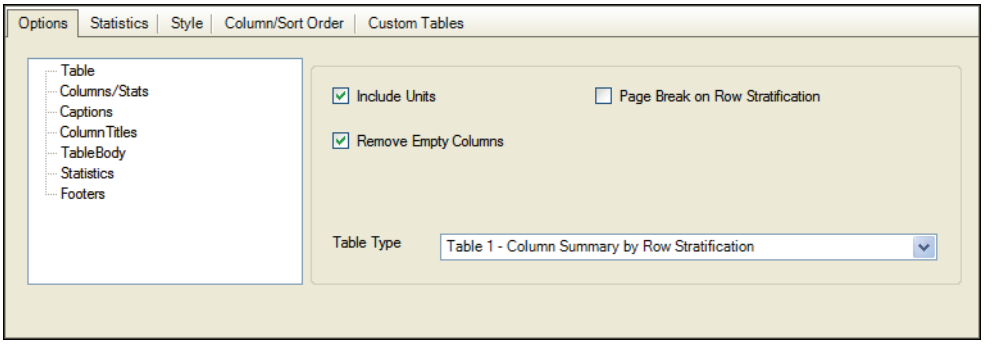
     or
   - In the Table's **Main** Mappings panel click the **Select source** button to open the **Select Object** dialog.

- Click the (+) signs beside **Install Test>Data** to expand the menu tree.
- Select **Bguide1** and click **Select**.

The Bguide1 data set is mapped to the Table object.

Use the **Options** tab to specify which table type the Table object uses. The Options tab is located underneath the Setup tab.

Table Options tab



3. In the **Table Type** menu, select `Table 1 - Column Summary by Row Stratification`.
4. Select the **Page Break on Row Stratification** check box.
5. Use the option buttons in the **Main** Mappings panel to map the data types to the following contexts:
   - Map **Subject** to the Stratification Row context.
   - Leave **Time** mapped to None.
   - Map **Conc** to the Data context.
6. Select the **Statistics** tab, which is located underneath the Setup tab.
7. Click the **Select All** Select All button to select all output statistics.
8. Click the **Execute** button. The Results are displayed on the Results tab.

The results are presented as three HTML tables. Compare the tables in the Results tab to the tables pictured below.

Tables 1 and 2

Subject		Conc
DW	N	16
	NMiss	0
	Nobs	16
	Mean	4.004
	SD	1.432
	SE	0.358
	Variance	2.051
	Min	1.39
	Median	4.10
	Max	6.20
	Range	4.81
	CV%	35.8
	Harmonic Mean	3.434
	Pseudo SD	1.7578
	Mean Log	1.3179
	SD Log	0.4039
	Geometric Mean	3.736
	CV% Geometric Mean	42.099
	CI 95% Lower	0.951
	CI 95% Upper	7.057
	CI 95% Lower Mean	3.241
	CI 95% Upper Mean	4.767
	CI 95% Lower Var	1.119
	CI 95% Upper Var	4.914
	Lower 1SD	2.572
	Upper 1SD	5.436
	CI GEO 95% Lower	1.579
	CI GEO 95% Upper	8.837
	CI 95% Lower GEO Mean	3.012
	CI 95% Upper GEO Mean	4.633
	GEO Lower 1SD	2.494
	GEO Upper 1SD	5.595
	1%	1.39
	5%	1.39
	10%	2.15
	25%	2.90
	50%	4.10
	75%	5.14
	90%	6.11
	95%	6.20
	99%	6.20
	Skewness	0.0537
	Kurtosis	-0.9299
	KS PValue	0.96

Subject		Conc
GS	N	16
	NMiss	0
	Nobs	16
	Mean	3.748
	SD	1.394
	SE	0.348
	Variance	1.942
	Min	1.29
	Median	3.70
	Max	6.47
	Range	5.18
	CV%	37.2
	Harmonic Mean	3.141
	Pseudo SD	1.7519
	Mean Log	1.2432
	SD Log	0.4334
	Geometric Mean	3.467
	CV% Geometric Mean	45.462
	CI 95% Lower	0.777
	CI 95% Upper	6.718
	CI 95% Lower Mean	3.005
	CI 95% Upper Mean	4.490
	CI 95% Lower Var	1.060
	CI 95% Upper Var	4.652
	Lower 1SD	2.354
	Upper 1SD	5.141
	CI GEO 95% Lower	1.376
	CI GEO 95% Upper	8.732
	CI 95% Lower GEO Mean	2.752
	CI 95% Upper GEO Mean	4.367
	GEO Lower 1SD	2.247
	GEO Upper 1SD	5.348
	1%	1.29
	5%	1.29
	10%	1.51
	25%	2.83
	50%	3.70
	75%	4.69
	90%	5.86
	95%	6.47
	99%	6.47
	Skewness	0.0473
	Kurtosis	-0.4740
	KS PValue	0.99

Table 3

Subject		Conc
RH	N	16
	NMiss	0
	Nobs	16
	Mean	4.154
	SD	1.502
	SE	0.375
	Variance	2.255
	Min	1.29
	Median	4.20
	Max	6.60
	Range	5.31
	CV%	36.2
	Harmonic Mean	3.503
	Pseudo SD	2.0453
	Mean Log	1.3500
	SD Log	0.4241
	Geometric Mean	3.857
	CV% Geometric Mean	44.386
	CI 95% Lower	0.953
	CI 95% Upper	7.355
	CI 95% Lower Mean	3.354
	CI 95% Upper Mean	4.954
	CI 95% Lower Var	1.231
	CI 95% Upper Var	5.402
	Lower 1SD	2.652
	Upper 1SD	5.656
	CI GEO 95% Lower	1.562
	CI GEO 95% Upper	9.524
	CI 95% Lower GEO Mean	3.077
	CI 95% Upper GEO Mean	4.835
	GEO Lower 1SD	2.524
	GEO Upper 1SD	5.895
	1%	1.29
	5%	1.29
	10%	2.05
	25%	2.98
	50%	4.20
	75%	5.19
	90%	6.51
	95%	6.60
	99%	6.60
	Skewness	-0.0027
	Kurtosis	-0.6773
	KS PValue	1.00

Confirm model functions

This section tests examples of noncompartmental analysis, pharmacokinetic modeling, bioequivalence, and population modeling.

Noncompartmental analysis

1. In the **File** menu select **Import** or click the **Import** **button**. The **Open File(s)** dialog is displayed.
2. Navigate to the Phoenix examples subdirectory, which by default is located at `C:\Program Files\Pharsight\Phoenix\application\Examples`.
3. Select the `Legacy WinNonlin` subdirectory.
4. In the **Files of type** menu select WinNonlin Files (`*.cmd;*.pco;*.pmo;*.pto;*.pwo`).
5. Select `Profiles.pmo` and click **Open**.

The **Data Import Wizard** is displayed. The wizard is used to assign options for how the data are imported and presented.

6. Click **Finish**. The data set is added to the project's **Data** folder.

A file in PMO (Pharsight Model Object) format is added to the Data folder as one or more workbook objects. A .pmo file also adds one or more operational objects to the project.

The `Profiles.pmo` file adds:

- A data set in workbook form (profiles).
- Data sets in workbook form for partial areas and dosing (Profiles_sources).
- An NCA model object (model 200) named Profiles.

7. Click the (+) symbols beside **profiles** and **Profiles_sources** in the Data folder to view the data sets' worksheets.
8. Select the NCA model object **Profiles** in the Object Browser. The NCA object's Setup tab is displayed in the right viewing panel.

CAUTION: Models saved in PMO format contain all the necessary data mappings and option settings. Do not change these settings.

9. Select items in the NCA model object's Setup tab list to explore the model's data mappings and option settings.
10. Click the **Execute** **button.** The Results are displayed on the Results tab.

Text Output

The **Core output** contains the model settings and the same data as the worksheets, but presented in plain ASCII text. If there were errors in the model they would be listed here.

Core output text file

Subject=1,Form=Capsule

Date: 4/29/2009
Time: 13:39:21

WINNONLIN NONCOMPARTMENTAL ANALYSIS PROGRAM
1.0
Core Version 04Jun2007

Settings

Model: Plasma Data, Extravascular Administration
Number of nonmissing observations: 12
Dose time: 0.00
Dose amount: 100.00
Calculation method: Linear Trapezoidal with Linear Interpolation
Weighting for lambda_z calculations: Uniform weighting
Lambda_z method: Find best fit for lambda_z, Log regression

Summary Table

Time min	Conc. ng/ml	Pred. ng/ml	Residual ng/ml	AUC min*ng/ml	AUMC min*min*ng/ml	Weight
0.0000	0.0000		0.0000	0.0000		
5.000	340.3		850.8	4254.		
10.00	1914.		6487.	5.636e+004		
15.00	2069.		1.644e+004	1.818e+005		
20.00	1471.		2.529e+004	3.329e+005		
30.00	788.8		3.659e+004	5.983e+005		
45.00 *	496.4	460.9	35.54	4.623e+004	9.434e+005	1.000
60.00 *	372.8	357.2	15.63	5.275e+004	1.279e+006	1.000
90.00 *	204.3	214.6	-10.33	6.141e+004	1.890e+006	1.000
120.0 *	124.1	128.9	-4.852	6.633e+004	2.389e+006	1.000
180.0 *	39.25	46.52	-7.266	7.123e+004	3.048e+006	1.000
240.0 *	19.32	16.79	2.531	7.299e+004	3.399e+006	1.000

The **Settings** file lists all the settings used to specify the noncompartmental analysis.

Settings text file

```
/********************************* Begin Mappings *********************************/
Main : install Test.Data.profiles.Sheet1
Sort : Subject, Form
Carry :
Time : Time
Concentration : Conc

Dosing : install Test.Data.Profiles_sources.Dosing
Sort : Subject, Form
Dose : Dose
Time of Dose : Time
Tau : Tau

Slopes : (Internal)

Partial Areas : install Test.Data.Profiles_sources.PartialAreas
Sort : Subject, Form
Area # : Curve
Label :
Start Time : Lower
End Time : Upper

Therapeutic Response : (Internal)

Units : (Internal)

Parameter Names : <None>

/********************************* End Mappings   *********************************/


Plasma Model
Linear Trapezoidal Linear Interpolation
Sparse = False
Dose Type = Extravascular
Dose Normalization = None
Exclude Insufficient Profiles = False
```

Output Data

The NCA object creates seven results worksheets: Dosing Used, Exclusions, Final Parameters, Final Parameters Pivoted, Plot Titles, Summary Table, and Partial Area Labels. Selections from the Final Parameters and Summary Table worksheets are shown below.

Final Parameters worksheet

	Subject	Form	Parameter	Units	Estimate
1	1	Capsule	Rsq		0.99267305
2	1	Capsule	Rsq_adjusted		0.99084131
3	1	Capsule	Corr_XY		-0.99632979
4	1	Capsule	No_points_lambda_z		6
5	1	Capsule	Lambda_z	1/min	0.016987622
6	1	Capsule	Lambda_z_lower	min	45
7	1	Capsule	Lambda_z_upper	min	240
8	1	Capsule	HL_Lambda_z	min	40.803072
9	1	Capsule	Tlag	min	0
10	1	Capsule	Tmax	min	15
11	1	Capsule	Cmax	ng/ml	2069.167
12	1	Capsule	Cmax_D	ng/ml/ng	20.69167
13	1	Capsule	Tlast	min	240
14	1	Capsule	Clast	ng/ml	19.31667
15	1	Capsule	AUClast	min*ng/ml	72987.921
16	1	Capsule	AUCall	min*ng/ml	72987.921
17	1	Capsule	AUCINF_obs	min*ng/ml	74125.023
18	1	Capsule	AUCINF_D_obs	min*ng/ml/ng	741.25023
19	1	Capsule	AUC_%Extrap_obs	%	1.5340334
20	1	Capsule	Vz_F_obs	ml	0.079415003
21	1	Capsule	Cl_F_obs	ml/min	0.0013490721
22	1	Capsule	AUCINF_pred	min*ng/ml	73976.044
23	1	Capsule	AUCINF_D_pred	min*ng/ml/ng	739.76044
24	1	Capsule	AUC_%Extrap_pred	%	1.3357341
25	1	Capsule	Vz_F_pred	ml	0.079574936
26	1	Capsule	Cl_F_pred	ml/min	0.001351789
27	1	Capsule	AUMClast	min*min*ng/ml	3398545.5
28	1	Capsule	AUMCINF_obs	min*min*ng/ml	3738387.3
29	1	Capsule	AUMC_%Extrap_obs	%	9.090598
30	1	Capsule	AUMCINF_pred	min*min*ng/ml	3693862.3
31	1	Capsule	AUMC_%Extrap_pred	%	7.9947977
32	1	Capsule	MRTlast	min	46.563122
33	1	Capsule	MRTINF_obs	min	50.433539
34	1	Capsule	MRTINF_pred	min	49.933223
35	1	Capsule	AUC0_120	min*ng/ml	66331.921

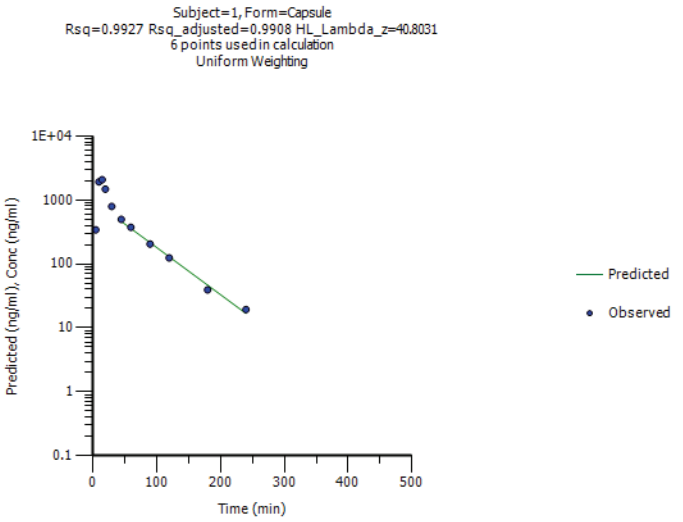
Summary Table worksheet

	Subject	Form	Time (min)	lambda_z_Incl	Conc (ng/ml)	Predicted (ng/ml)	Residual (ng/ml)	AUC (min*ng/ml)	AUMC (min*min*ng/ml)	Weighting
1	1	Capsule	0		0			0	0	0
2	1	Capsule	5		340.3167			850.79175	4253.9588	0
3	1	Capsule	10		1914			6486.5835	56357.918	0
4	1	Capsule	15		2069.167			16444.501	181801.68	0
5	1	Capsule	20		1470.917			25294.711	332941.29	0
6	1	Capsule	30		788.75			36593.046	598345.49	0
7	1	Capsule	45	*	496.4167	460.87344	35.543259	46231.796	943354.88	1
8	1	Capsule	60	*	372.8333	357.20475	15.628553	52751.171	1278670.5	1
9	1	Capsule	90	*	204.25	214.57954	-10.329536	61407.421	1889958	1
10	1	Capsule	120	*	124.05	128.90192	-4.8519188	66331.921	2388985.5	1
11	1	Capsule	180	*	39.25	46.515912	-7.2659123	71230.921	3047515.5	1
12	1	Capsule	240	*	19.31667	16.785864	2.5308059	72987.921	3398545.5	1
13	1	Tablet	0		0			0	0	0
14	1	Tablet	5		1474.2			3685.5	18427.5	0
15	1	Tablet	10		2475			13558.5	98730	0
16	1	Tablet	15		949.3			22119.25	196203.75	0
17	1	Tablet	20		665.7			26156.75	265087.5	0
18	1	Tablet	30		426.6			31618.25	395647.5	0
19	1	Tablet	45		293.3			37017.5	590621.25	0
20	1	Tablet	60		232			40957.25	794010	0
21	1	Tablet	90		168.6			46966.25	1230420	0
22	1	Tablet	120		108.4			51121.25	1653150	0
23	1	Tablet	180	*	45.7	52.948237	-7.2482367	55744.25	2290170	1
24	1	Tablet	240	*	15.2	12.18823	3.0117702	57571.25	2646390	1
25	1	Tablet	360	*	0.6	0.64583102	-0.04583102	58519.25	2878230	1

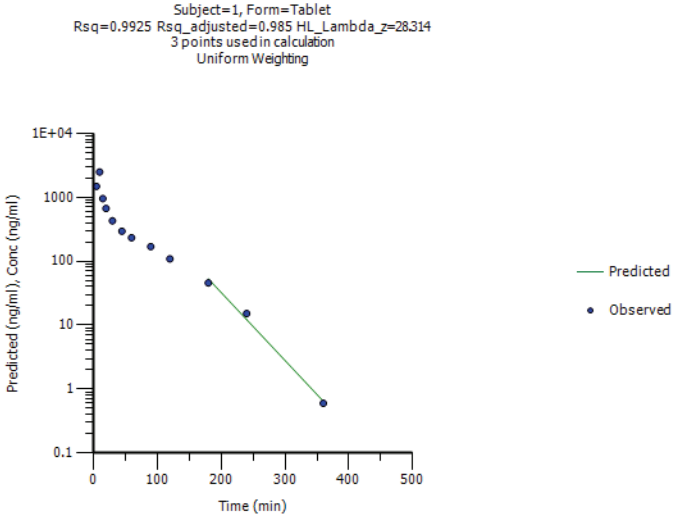
Plots

A total of 12 plots are generated; one for each of two formulations, for each of the six subjects. The first two charts for subject one are shown below.

Observed Y and Predicted Y vs X for Subject 1



Observed Y and Predicted Y vs X for Subject 1



Pharmacokinetic modeling

1. In the **File** menu select **Import** or click the **Import** button. The **Open File(s)** dialog is displayed.
2. Navigate to the Phoenix examples subdirectory, which by default is located at `C:\Program Files\Pharsight\Phoenix\application\Examples`.
3. Select the `Legacy WinNonlin` subdirectory.
4. In the **Files of type** menu select WinNonlin Files (`*.cmd;*.pco;*.pmo;*.pto;*.pwo`).
5. Select `Exp1.pmo` and click **Open**.

The **Data Import Wizard** is displayed. The wizard is used to assign options for how the data are imported and presented.

6. Click **Finish**. The data set is added to the project's **Data** folder.

The `Exp1.pmo` file adds:

- A data set in workbook form (exp1).
- Data sets in workbook form for dosing and the stripping dose (Exp1_sources).
- A PK Model object named Exp1.

7. Click the (+) symbols beside **exp1** and **Exp1_sources** in the Data folder to view the data sets' worksheets.
8. Select the PK Model object **Exp1** in the Object Browser. The PK Model object's Setup tab is displayed in the right viewing panel.
9. Select items in the PK Model object's Setup tab list to explore the model's data mappings and option settings.

The imported PK Model object uses PK Model 13, which is a two compartment model with 1st order absorption.

10. Click the **Execute** button. The Results are displayed on the Results tab.

Worksheet results

The PK Model object's output worksheets partially include Condition Numbers, Diagnostics, Dosing Used, Final Parameters, Initial Estimates, Secondary Param-

eters, and Summary Table. The Final Parameters, Secondary Parameters, and Summary Table worksheets are shown below.

Final Parameters worksheet

	Parameter	Units	Estimate	StdError	CV%	UnivarCI_Lower	UnivarCI_Upper	PlanarCI_Lower	PlanarCI_Upper
1	A	ng/ml	30.716921	204.06447	664.33894	-418.42766	479.8615	-792.61493	854.04877
2	B	ng/ml	4.9730197	0.13656732	2.7461649	4.6724359	5.2736035	4.4220163	5.5240232
3	K01	1/hr	2.6942115	1.9405098	72.025149	-1.5768382	6.9652611	-5.1350965	10.523519
4	Alpha	1/hr	2.0910843	1.7982089	85.994087	-1.8667618	6.0489305	-5.1640868	9.3462554
5	Beta	1/hr	0.053250343	0.0028018144	5.2615894	0.047083568	0.059417118	0.041945959	0.064554727

Secondary Parameters worksheet

	Parameter	Units	Estimate	StdError	CV%
1	K10	1/hr	0.12391417	0.08659311	69.881522
2	K12	1/hr	1.1218069	1.5425864	137.50908
3	K21	1/hr	0.89861356	0.18279148	20.3415
4	AUC	hr*ng/ml	94.832014	3.2679905	3.4460836
5	K01_HL	hr	0.25727274	0.18511596	71.953196
6	K10_HL	hr	5.5937684	3.8951509	69.633754
7	Alpha_HL	hr	0.3314774	0.28476619	85.908179
8	Beta_HL	hr	13.016765	0.6842045	5.2563331
9	V1_F	ml	0.17019784	0.11681018	68.631998
10	CL_F	ml/hr	0.021089924	0.00072818238	3.4527501
11	V2_F	ml	0.21247077	0.10752274	50.605899
12	CLD2_F	ml/hr	0.19092911	0.13182713	69.045063
13	Tmax	hr	0.64378578	0.021305298	3.309377
14	Cmax	ng/ml	6.4998293	0.11381627	1.7510655

Summary table worksheet

	Time_obs (hr)	Conc_obs (ng/ml)	Time (hr)	Conc (ng/ml)	Predicted (ng/ml)	Residual (ng/ml)	Weighting	SE_Yhat	Standard_Res	WPredicted	WResidual
1	0.1	2.6	0.1	2.6	2.6067253	-0.0067253447	1.3473146	0.087138063	-0.088365042	3.0257273	-0.007806368
2	0.25	4.817	0.25	4.817	4.9204821	-0.10348206	0.72721984	0.10267595	-0.86666477	4.1960486	-0.08824659
3	0.5	6.596	0.5	6.596	6.3603071	0.23569286	0.53108217	0.10998709	1.5940847	4.6350983	0.17176208
4	0.75	6.471	0.75	6.471	6.4482695	0.022730487	0.54134106	0.11366078	0.15916142	4.7443712	0.016724156
5	1	6.049	1	6.049	6.0978174	-0.048817413	0.57910696	0.10292682	-0.3405562	4.6403828	-0.037149601
6	1.5	5.314	1.5	5.314	5.2980283	0.015971692	0.65920549	0.10377866	0.12400906	4.3015471	0.012967651
7	2	4.611	2	4.611	4.7764491	-0.16544911	0.75970895	0.091358023	-1.3335515	4.1632144	-0.14420757
8	2.5	4.5	2.5	4.5	4.4755802	0.024419815	0.77844844	0.069751507	0.18050631	3.9487921	0.021545536
9	3	4.392	3	4.392	4.2856947	0.10630533	0.79759061	0.063277092	0.77931503	3.8274651	0.094939088
10	4	4.013	4	4.013	4.0253838	-0.012383783	0.87291751	0.068268754	-0.097903963	3.7609183	-0.011570175
11	5	3.698	5	3.698	3.8113916	-0.11339162	0.94727365	0.06502222	-0.93174262	3.7095506	-0.11036178
12	6	3.505	6	3.505	3.6130579	-0.10805793	0.99943451	0.05850305	-0.89361557	3.6120362	-0.10802738
13	8	3.382	8	3.382	3.2479532	0.13404682	1.035783	0.048970215	1.0939971	3.3055531	0.13642403
14	12	2.844	12	2.844	2.6248484	0.21915164	1.2317222	0.048440336	1.9764024	2.913135	0.24322102
15	14	2.383	14	2.383	2.3596716	0.023328436	1.4700033	0.052299454	0.23892811	2.860953	0.028284257
16	24	1.287	24	1.287	1.3854417	-0.098441709	2.7218477	0.064753651	-1.9958321	2.2857049	-0.16240936

Text Output

The **Core output** text results include all model settings and iterations, including the output from the worksheets. Any model errors would be listed here.

Core output text file

```
WinNonlin 6.0.0.1645, WnlPKCore Library: 1.0.5.0
                                        Date:   04/29/2009
                                        Time:     14:35:48

              WINNONLIN NONLINEAR ESTIMATION PROGRAM
                   Core Version 18June2007




 Listing of input commands

 TITL 1
 Example one - Fitting model 13 in the compiled library : single dose
 TITL 2
 Using Weight Command and Curve Stripping to get Initial Estimates

 MODEL 13
 NVAR 2
 NPOI 1000
 XNUM 1
 YNUM 2
 NCON 4
 CONS 2,1,2,0
 METH 2'Gauss-Newton (Levenberg and Hartley)
 ITER 50
 WEIG -1
 MISS 'Missing'
 DATA 'WINNLIN.DAT'
 BEGI


 Computation of initial estimates completed.
```

The **Settings** file lists all the settings used to specify the noncompartmental analysis.

Settings text file

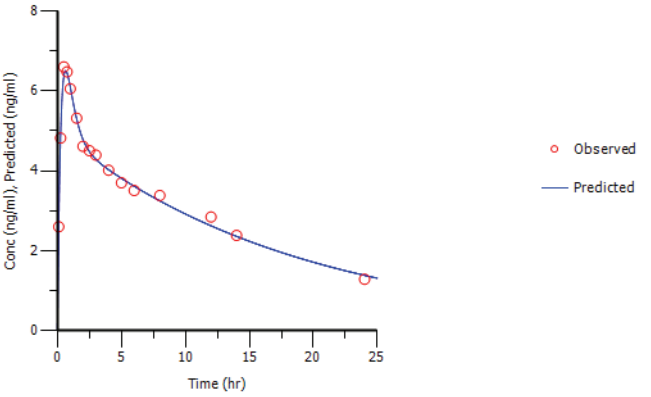
```
/******************************** Begin Mappings ********************************/
Main : install Test.Data.exp1.Sheet1
Sort :
Time : Time
Concentration : Conc
Carry :

Dosing : install Test.Data.Exp1_sources.Dosing
Sort :
Time : Time
Dose : Dose

Initial Estimates : (Internal)

Units : (Internal)

Stripping Dose : install Test.Data.Exp1_sources.Stripping
Sort :
Dose : Dose


***** Other Parameters *****


/******************************** End Mappings   ********************************/


PK 13 - [Exp1]
Gauss-Newton (Levenberg and Hartley)
Convergence criteria of 0.0001 used during minimization process
50 maximum iterations allowed during minimization process
Weighted analysis using WEIGHT = -1
```

Plots

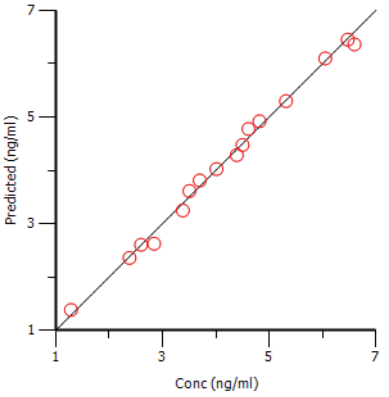
The plot results include Observed Y and Predicted Y vs X, Partial Derivatives Plot, Predicted Y vs Observed Y, Residual Y vs Predicted Y, Residual Y vs X, Weighted Predicted Y vs Observed Y, Weighted Residual Y vs Weighted Predicted Y, and Weighted Residual Y vs X.

Some plot results are shown below.

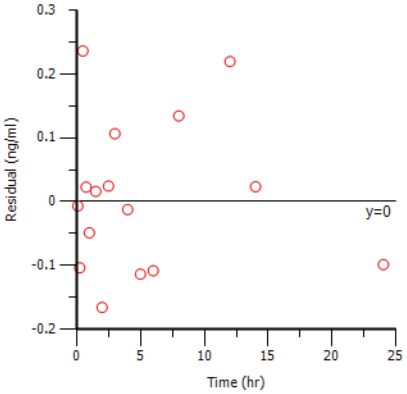
Observed Y and Predicted Y vs X



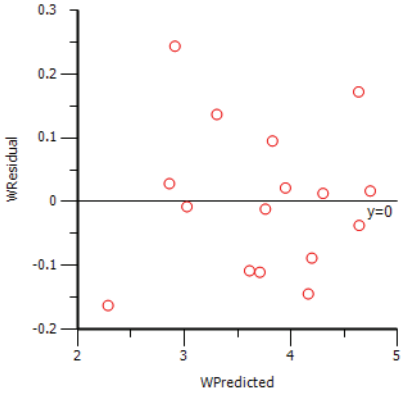
Predicted Y vs Observed Y



Residual Y vs X



Weighted Residual Y vs Weighted Predicted Y



Bioequivalence

Import the data:

1. In the **File** menu select **Import** or click the **Import** **button**. The **Open File(s)** dialog is displayed.
2. Navigate to the Phoenix examples subdirectory, which by default is located at `C:\Program Files\Pharsight\Phoenix\application\Examples`.

3. In the **Files of type** menu select ASCII Data (`*.csv;*.dat`).
4. Select the file `Seq2Per4.csv` and click **Open**.

The **Worksheet Import Options** dialog is displayed. The dialog is used to assign options for how the data are imported and presented.

5. Click **Finish**. The data set is added to the project's **Data folder**.

Set up the average bioequivalence model:

1. Select the workflow in the Object Browser. In the **Insert** menu select **NCA and Toolbox>Bioequivalence**.

The **Bioequivalence** object is added to the workflow in the Object Browser.

Note: The default settings for a new Bioequivalence model are *Crossover* as the type of study and *Average* as the type of bioequivalence.

2. Map the data set **Seq2Per4** as the input source for the Bioequivalence object:
   - Use the pointer to drag the **Seq2Per4** worksheet from the Data folder to the **Main** Mappings panel.

     or
   - In the Bioequivalence **Main** Mappings panel click the **Select source** button to open the **Select Object** dialog.
   - Click the (+) signs beside **Install Test>Data** to expand the menu tree.
   - Select the **Seq2Per4** worksheet and click **Select**.

The Seq2Per4 data set is mapped to the Bioequivalence object.

3. Use the option button in the **Main** Mappings panel to map **AUC** to the Dependent context.

» The following data types are automatically mapped to contexts when the data set is mapped to the Bioequivalence model.
- **Sequence** is mapped to the Sequence context.
- **Subject** is mapped to the Subject context.
- **Period** is mapped to the Period context.
- **Formulation** is mapped to the Formulation context.

Use the Model tab to specify settings for Bioequivalence model options. The Model tab is located underneath the Setup tab.

4. Ensure that **Crossover** is selected as the Type of study, **Average** is selected as the Type of Bioequivalence, and **R** is selected as the Reference Formulation.
5. Select the **Fixed Effects** tab, which is located underneath the Setup tab.
   - `Ln(x)` is automatically selected in the **Dependent Variables Transformation** menu. Do not change this setting.
6. Click the **Execute** button. The Results are displayed on the Results tab.

Output Data

The bioequivalence model's worksheet output partially includes Average Bioequivalence, Diagnostics, Final Fixed Parameters, Final and Initial Variance

Parameters, Least Squares Means, and Sequential Tests. The Diagnostics, Final Variance Parameters, and Sequential Tests worksheets are shown below.

Diagnostics

	Dependent	Units	Diagnostic	Value
1	Ln(AUC)		Total Observatio	000000000048
2	Ln(AUC)		Observations Us	000000000048
3	Ln(AUC)		Obs. Missing Mo	000000000000
4	Ln(AUC)		Residual SS	0
5	Ln(AUC)		Residual df	000000000000
6	Ln(AUC)		Convergence	Achieved
7	Ln(AUC)		REML log(likelih	-19.238555
8	Ln(AUC)		-2 * REML log(li	38.477111
9	Ln(AUC)		Akaike's Inform	60.477111
10	Ln(AUC)		Schwarz's Bayes	79.591476
11	Ln(AUC)		Hessian eigenva	855.2051
12	Ln(AUC)		Hessian eigenva	715.32814
13	Ln(AUC)		Hessian eigenva	158.63358
14	Ln(AUC)		Hessian eigenva	63.03212
15	Ln(AUC)		Hessian eigenva	21.604278

Final Variance Parameters

	Dependent	Units	Parameter	Estimate
1	Ln(AUC)		lambda(1,1)_11	0.27893988
2	Ln(AUC)		lambda(1,2)_11	0.35567907
3	Ln(AUC)		lambda(2,2)_11	-1.97E-13
4	Ln(AUC)		Var(Period*For	0.10761781
5	Ln(AUC)		Var(Period*For	0.09035641

Sequential Tests

	Dependent	Units	Hypothesis	Numer_DF	Denom_DF	F_stat	P_value
1	Ln(AUC)		int	1	10.008139	3055.0348	8.9E-14
2	Ln(AUC)		Sequence	1	10.008139	0.095274924	0.7639047
3	Ln(AUC)		Formulation	1	24.829354	4.328066	0.047965077
4	Ln(AUC)		Period	3	28.392036	2.1673487	0.11384356

Import the data:

1. In the **File** menu select **Import** or click the **Import** **button**. The **Open File(s)** dialog is displayed.
2. Navigate to the Phoenix examples subdirectory, which by default is located at `C:\Program Files\Pharsight\Phoenix\application\Examples`.
3. In the **Files of type** menu select ASCII Data (`*.csv;*.dat`).
4. Select the file `RTR_TRT.csv` and click **Open**.

The **Worksheet Import Options** dialog is displayed. The dialog is used to assign options for how the data are imported and presented.

5. Click **Finish**. The data set is added to the project's **Data folder**.

Set up the population/individual bioequivalence model:

1. Select the workflow object in the Object Browser. In the **Insert** menu select **NCA and Toolbox>Bioequivalence**.

The **Bioequivalence** object is added to the workflow in the Object Browser.

Note: When multiple objects of the same type are added to a workflow they are numbered sequentially. For example, the second Bioequivalence Model object added to this workflow is called Bioequivalence 1.

2. Map the data set **RTR_TRT** as the input source for the Bioequivalence 1 object:
   - Use the pointer to drag the **RTR_TRT** worksheet from the Data folder to the **Main** Mappings panel.

     or
   - In the Bioequivalence 1's **Main** Mappings panel click the **Select source** button to open the **Select Object** dialog.
   - Click the (+) signs beside **Install Test>Data** to expand the menu tree.
   - Select the **RTR_TRT** worksheet and click **Select**.

The RTR_TRT data set is mapped to the Bioequivalence 1 object.

3. Use the option buttons in the **Main** Mappings panel to map the data types to the following contexts:
   - Map **Sequence** to the Sequence context.
   - Map **Subject** to the Subject context.
   - Map **Period** to the Period context.
   - Map **Trt** to the Formulation context.
   - Map **AUC** to the Dependent context.

Use the Model tab to specify settings for Bioequivalence model options. The Model tab is located underneath the Setup tab.

4. In the Model tab, select the **Population/Individual** option button.

Note: Crossover is the only study type allowed for the Population/Individual Bioequivalence model.

- R is automatically selected in the **Reference Value** menu. Do not change this setting.

5. Click the **Execute** button. The Results are displayed on the Results tab.

The output includes analysis settings and results, and three worksheets. The first two worksheets are shown below.

Population/Individual worksheet

	Dependent	Units	Statistic	Value	Upper_CI	Conclusion
1	Ln(AUC)		Difference(Delta)	-0.48193057		
2	Ln(AUC)		Ratio(%Ref)	61.758994		BE not shown for ratio test
3	Ln(AUC)		SigmaR	0.72246983		
4	Ln(AUC)		SigmaWR	0.36977619		
5	Ln(AUC)		Ref_Pop_eta	-0.57252481	0.27045421	Pop. BE not shown for refnc-scaling CI test
6	Ln(AUC)		Const_Pop_eta	0.33551622	1.0559302	Pop. BE not shown for const-scaling CI test
7	Ln(AUC)		Mixed_Pop_eta	-0.57252481	0.27045421	Pop. BE not shown for mixed-scaling CI test
8	Ln(AUC)		Ref_Indiv_eta	0.44889837	1.2047035	Indiv. BE not shown for refnc-scaling CI test
9	Ln(AUC)		Const_Indiv_eta	0.69023394	1.4180961	Indiv. BE not shown for const-scaling CI test
10	Ln(AUC)		Mixed_Indiv_eta	0.44889837	1.2047035	Indiv. BE not shown for mixed-scaling CI test

Ratios Test=T

	Dependent	Units	Subject	Sequence	R	T	Test_Ref	Ratio_PctRef
1	Ln(AUC)		1	1	109.39956	45.6	-63.799557	41.68207
2	Ln(AUC)		2	1	39.648228	49.4	9.7517718	124.59573
3	Ln(AUC)		3	1	12.490452	11.13	-1.3604524	89.108062
4	Ln(AUC)		4	1	55.149433	15.33	-39.819433	27.797203
5	Ln(AUC)		5	1	17.726545	34.47	16.743455	194.45414
6	Ln(AUC)		6	1	52.453488	16.61	-35.843488	31.66615
7	Ln(AUC)		7	1	46.063265	25.79	-20.273265	55.988215
8	Ln(AUC)		8	1	42.734667	46.53	3.7953326	108.88116
9	Ln(AUC)		9	1	34.291133	69.41	35.118867	202.41384
10	Ln(AUC)		10	1	19.105601	12.81	-6.2956013	67.0484
11	Ln(AUC)		11	2	137	18.450659	-118.54934	13.467634
12	Ln(AUC)		12	2	14.44	4.8509174	-9.5890826	33.593611
13	Ln(AUC)		13	2	41.68	29.816448	-11.863552	71.536585
14	Ln(AUC)		14	2	108.85	81.860117	-26.989883	75.204517
15	Ln(AUC)		15	2	33.12	49.154641	16.034641	148.41377
16	Ln(AUC)		16	2	29.96	7.2420646	-22.717935	24.172445
17	Ln(AUC)		17	2	29.67	78.26	48.59	263.76812
18	Ln(AUC)		18	2	120.3	20.699652	-99.600348	17.206693

This concludes the installation tests.

Chapter 4

The Phoenix User Interface

Navigating the Phoenix application

This chapter presents an overview of the Phoenix user interface (UI). The different menu options, tabs, and panels that make up the Phoenix UI are described in the sections below. This chapter also discusses the arrangement of Phoenix functions and the location of data sources.

This section includes the following topics:

» "Phoenix User Interface" on page 63

» "Phoenix Menu Options" on page 64

– "Main menu options" on page 65

– "Toolbar buttons" on page 65

» "Phoenix Panels and Tabs" on page 67

– "Object Browser panel" on page 67

– "Diagram tab" on page 68

– "Setup tab" on page 69

– "Results tab" on page 70

– "Verification tab" on page 71

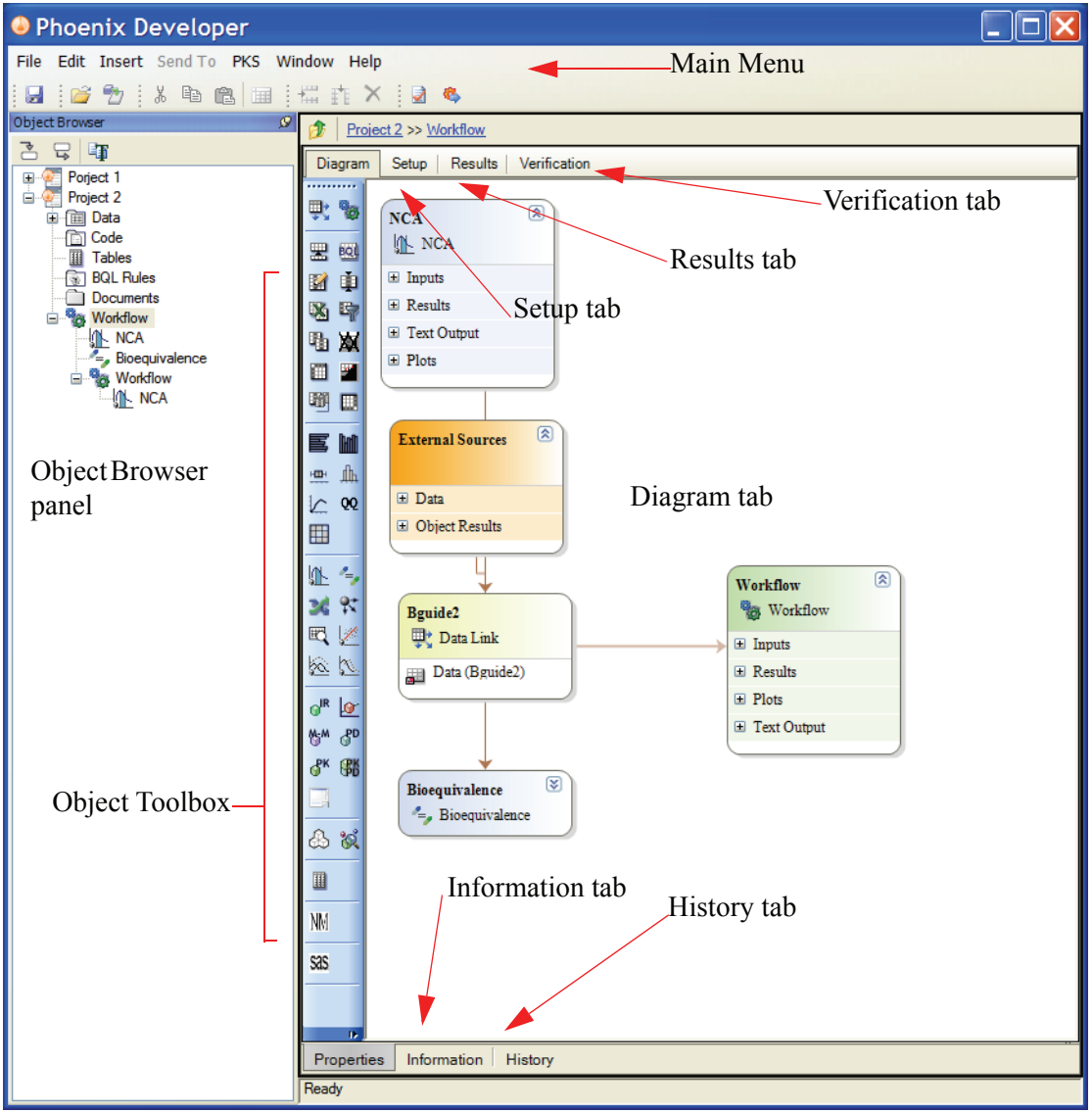
– "Information tab" on page 72

– "History Tab" on page 73

Phoenix User Interface

The Phoenix interface lets users control and organize multiple projects, workflows, operational objects, and data sources. This section describes the different parts of the Phoenix interface.

Phoenix main interface



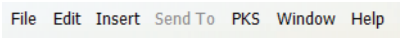
Phoenix Menu Options

The Phoenix main menu allows users to create and save projects, import data sets, export operational objects and worksheets, and connect to databases.

Note: All menu options are not always active. Inactive options are unavailable. Some options are only available when a user selects a certain part of the interface, such as a cell in a worksheet.

For example, the **Insert** menu is only available when a project, workflow, or operational object is selected. The **Send To** menu is only available when a worksheet is selected.

Main menu options



Phoenix menu bar

» **File** - create new and load existing projects, close projects, reload and save projects, import and export data sets and models, export to and import from a database, export to and import from S-PLUS data frames, export results to Microsoft Word, export models to NONMEM, connect to a database, and print results.

» **Edit** - undo and redo worksheet edits, cut, copy and paste worksheet cells, insert and delete rows and columns, freeze panes, and access the Preferences dialog.

» **Insert** - allows users to insert operational objects into a workflow. The Insert menu is only available when a project, a workflow object, or an operational object is selected.

» **Send To** - allows users to send worksheets to an operational object. The Send To menu is only available when a worksheet is selected.

» **PKS** - allows users to connect to the Pharsight Knowledgebase Server (PKS), and create and edit studies.

» **Window** - allows users to close the Object Browser and arrange open MDI windows.

» **Help** - allows users to access Phoenix help content.

Toolbar buttons

Phoenix toolbar

» **Import** - allows users to import files into Phoenix. The following files types are supported:

– ASCII Data (*.csv;*.dat)

- Ascii model (*.lib)
- BQL Rule Set (*.phxruleset)
- Excel Files (*.xls)
- Image File (*.bmp;*.gif;*.jpeg;*.jpg;*.png)
- Legacy Settings (*.bql;*.tdf;*.xml)
- Legacy Workspace (*.wsp)
- LML File (*.lml)
- Phoenix Projects (*.phxproj)
- Phoenix Template (*.wnlt)
- RTF File (*.rtf)
- SAS Transport Files (*.xpt)
- Text (*;*.;*.bat;*.cmd;*.mdl;*.sas;*.ssc;*.txt;*.vbs)
- WinNonlin Files (*.cmd;*.map;*.pco;*.pmo;*.pto;*.pwo)
- All Files (*.*)

» **Export** - allows users to export workflows, operational objects, and worksheets.

Note: The following options are only available when a cell in a worksheet is selected.

» **Cut** - cut the value out of a cell.

» **Copy** - copy the value of a cell.

» **Paste** - paste a value into a cell.

» **Freeze Panes** - allows users to select a cell and “freeze” it into a fixed position. Users can then scroll up and down a worksheet relative to the frozen cell, which acts as a scroll limiter.

» **Insert Row** - inserts a row into a worksheet.

» **Insert Column** - inserts a column into a worksheet.

» **Delete** - delete rows or columns from a worksheet.

Note: The following options are only available when a workflow or operational object is selected.

» **Verify** - checks if an executable object can be run.

» **Execute** - executes an object or workflow, depending on which is selected in the Object Browser.

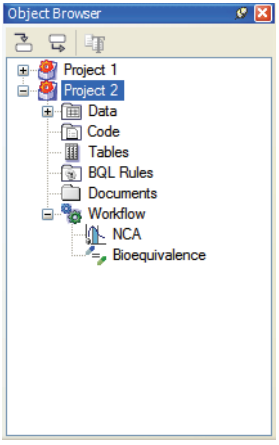
Phoenix Panels and Tabs

Phoenix uses a series of panels and tabs that allow users to create and edit projects, and view results and project information.

Object Browser panel

The Object Browser displays all the operational objects inserted into a project or a workflow.

Object Browser



The Object Browser contains the following items:

» **Project** - contains all the operational objects inserted into a project. Also contains the Data and Library folders.

» **Data folder** - the Data folder contains imported data sets and user-created worksheets and workbooks.

» **Code folder** - contains imported PML and legacy ASCII model code.

» **Tables folder** - contains imported or internally created output tables.

» **BQL Rules folder** - contains rules for importing data sets with uselessly low concentration data.

» **Documents folder** - contains any binary objects that do not belong in the other folders.

» **Workflow object** - an object that allows users to group operational object and nest workflows within a project.

» **Operational object** - any object that receives input, performs an operation, and produces results. An example is the NCA (noncompartmental analysis) object.

Object Browser toolbar buttons

Object Browser toolbar

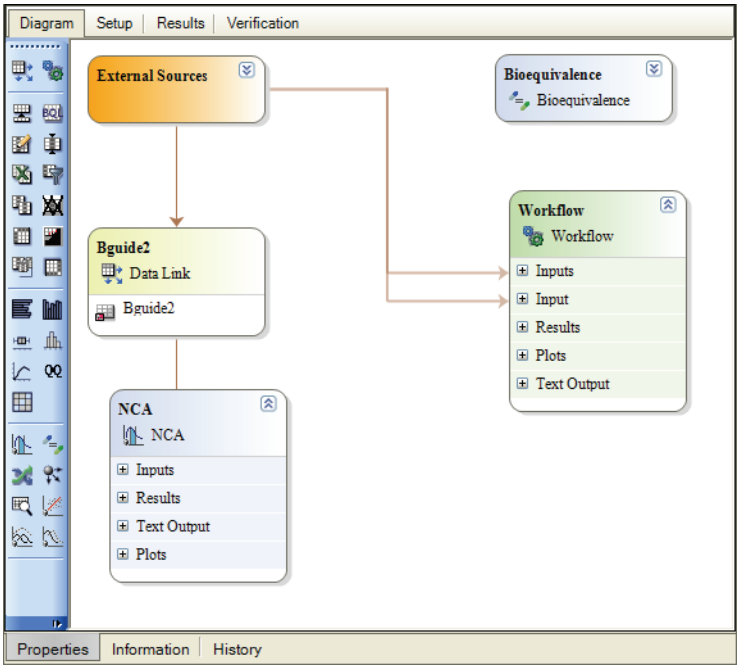
» **Show Sources** - shows which data is mapped to an operational object.

» **Show Dependents** - shows all objects which depend on the selected object for data input.

» **Create Template** - creates a template from a workflow object.

Diagram tab

Diagram tab



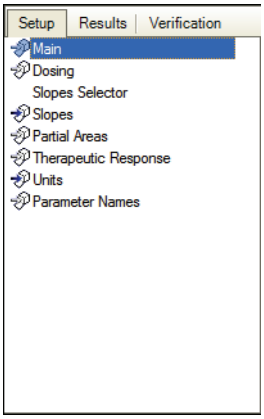
» Contains the operational objects in a workflow.

» Contains the Object Toolbox, which allows users to insert objects into a project by clicking the buttons in Object Toolbox.

» The objects in the Object Toolbox are grouped in the same way as they are in the Insert menu.

Setup tab

NCA Setup tab



» The Setup tab is the default view of any newly inserted operational object.

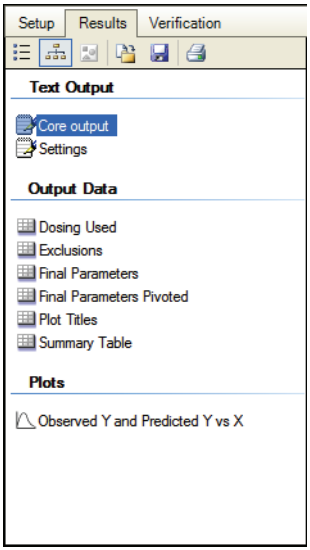
» The Setup tab gives users access options used to set up an operational object.

» The Setup tab contains a list of the panels and options tabs that are used to set up an operational object.

» The Setup tab allows users to map data sets and other worksheets to an operational object.

Results tab

NCA Results tab



» The Results tab displays the results of an executed object.

» Results are automatically grouped by type. Result types are text, worksheets, and graphs.

Results tab toolbar buttons

Results tab toolbar

» **Do not group** - does not group results.

» **Group by type** - groups results by type.

» **Group by executable** - groups results by executable object.

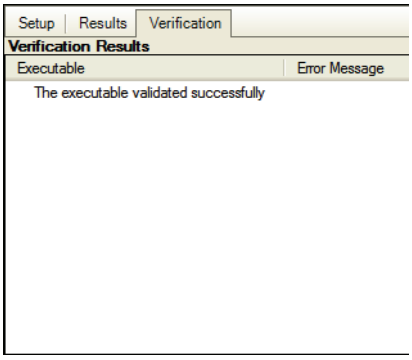
» **Copy to Data Folder** - copies results to the Data folder.

» **Export** - exports the results.

» **Print** - prints the results.

Verification tab

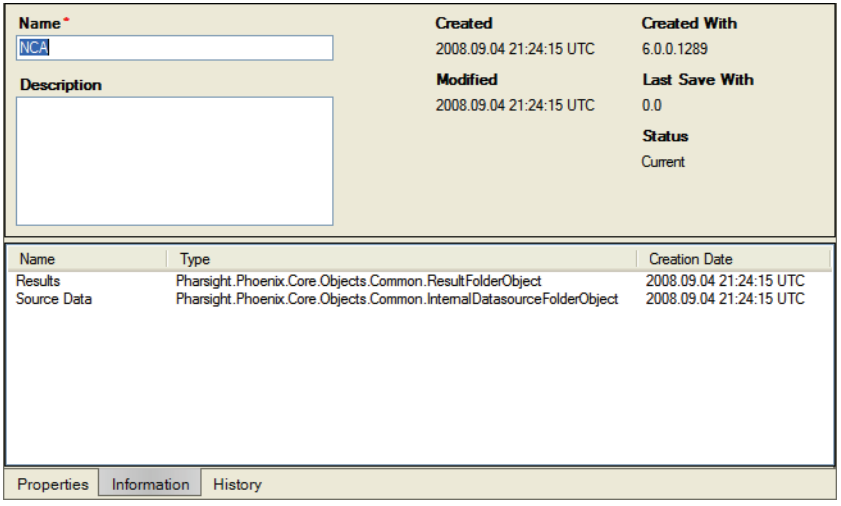
NCA Verification tab



» The Verification tab displays operational object status and execution error messages.

Information tab

NCA Information tab



» When a project is selected the tab displays information items in the project, including the name, type, creation date, and project status.

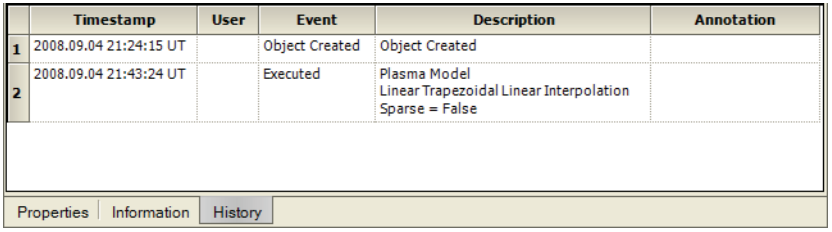
» When a workflow is selected the Information tab lists all the objects that are contained in the workflow. It also displays information about the object type and creation time.

» The Information tab displays information about a selected object. The name, date created, last date modified, the version of Phoenix used to create the object, and the status are displayed for each object.

» Imported data sets also have the Source Information displayed, which shows the location from where they were imported.

History Tab

NCA History tab



	Timestamp	User	Event	Description	Annotation
1	2008.09.04 21:24:15 UT		Object Created	Object Created	
2	2008.09.04 21:43:24 UT		Executed	Plasma Model Linear Trapezoidal Linear Interpolation Sparse = False	

Properties | Information | History

» Displays the history of selected projects, worksheets, workflows, and objects. Similar to the worksheet history tab in WinNonlin, but lists the history of any item selected in a project.

Chapter 5

Phoenix Concepts

An introduction to the Phoenix platform

Introduction

This chapter provides an overview of the Phoenix architecture, definitions of Phoenix-specific terms, and concepts used to describe work in Phoenix. Phoenix presents several new concepts and functions that users must be aware of in order to successfully use Phoenix. This chapter covers concepts and terminology new to Phoenix, including projects, workflows, objects, and templates.

This section includes the following topics:

» "Phoenix Architectural Overview" on page 75

» "Phoenix Terminology" on page 76

» "Phoenix Work Concepts" on page 80

– "Projects" on page 80

– "Workflows" on page 81

– "Operational Objects" on page 83

– "Templates" on page 85

– "Data" on page 86

Phoenix Architectural Overview

» Phoenix is based on a modular, or component based, framework. This design philosophy results in a flexible and robust application platform for future expansion, promotes interchangeability between major and minor system components, and permits third party development of new, specialized tools through the use of Pharsight's API (**A**pplication **P**rogramming **I**nterface).

» This type of architecture is called a plug-in architecture because components or **plug-ins**, which are discrete functional units in Phoenix, can be added and removed without affecting the core application. Each plug-in provides a specific function. Descriptive statistics, noncompartmental analysis, and linear mixed effects modeling are all **plug-ins** created for use with the Phoenix platform.

» A **plug-in** is a "black box" that performs some operation on input data and outputs the results. **Plug-ins** are referred to internally as **operational objects**. An operational object is an object in Phoenix that performs a function, such as analysis or data manipulation. An **operational object** is the smallest functional unit within Phoenix.

» Using Pharsight's API, any developer can create new functions and add those functions to the Phoenix platform without compromising the stability of the application. Phoenix at its core does not carry out any useful analytic tasks. Phoenix requires plug-ins in order to perform any meaningful analysis.

» Phoenix allows users to work in an MDI (**M**ultiple **D**ocument **I**nterface) or an SDI (**S**ingle **D**ocument **I**nterface) environment. Workflows, operational objects, and data sets can be opened in their own window separate from the main Phoenix interface, or users can choose to work completely within the Phoenix user interface.

Phoenix Terminology

This section contains terms that are unique to Phoenix and are used throughout the application.

» **BQL Rules folder** - contains BQL rule sets.

» **Code folder** - contains PML and WinNonlin ASCII code. Also contains NONMEM, S-PLUS, and SAS scripts, as well as any imported text or rich text format (*.rtf) files.

» **Columns tab** - tab used to display column headers when a worksheet is selected. The Columns tab allows users to change column header names, change column data types to either numeric or string, assign units to a column header, and change the way data is displayed a worksheet.

» **Context associations** - context associations are inputs in an operational object. These inputs must have a data type mapped to them. Examples of

context associations include sort, concentration, time, formulation, X-axis, Y-axis, etc.

» **Data folder** - contains all imported data sets, user-created data sets, and copies of results from operational objects. Data sets in the Data folder can be contained in workbooks or worksheets.

» **Data Link** - operational object that links one or more operational objects to the same data source. A Data Link is only accessible in the Diagram tab. Data Links allow users to create a place holder for input data that is shared between objects or workflows in a project.

» **Data Source -** when data such as a data set in the Data folder or results from an operational object are mapped to the input of an operational object, no data are physically transferred into that operational object. Instead, the operational object is pointed to the location of the data, whether it is in the Data folder or an operational object's results, and the information is directly read from that source.

» **Data type -** data types in Phoenix refer to two things:

1. **Study variables** and **output parameters**.
   - Study variables are the variables used in a drug trial and recorded in a data set. These include common variables such as subject IDs, nominal and actual sample times, concentration values, volume, treatment formulations, etc.
   - Output parameters are the results of an analysis. These include Tmax, Cmax, AUCall, Lambda_Z, Clss, Vz, etc.
   - Study variables and output parameters can be mapped to context associations, or inputs, in an operational object.
2. **Column data types**.
   - Numeric-type columns are considered by Phoenix to contain only numeric values, and the application treats the values in a numeric column as numeric data. A numeric column contains only numeric values or substitution values such as those applied by BQL rules.
   - Text-type columns in Phoenix can contain mixed numeric and text values, but Phoenix treats values in a text-type column as non-numeric values that cannot have certain operations performed on them, such as an arithmetic column transformation.

» **Diagram tab** - only available when viewing the workflow level. The Diagram tab displays a schematic of the connections between operational

objects in a project or workflow. The Diagram tab also shows the flow of the operational procedures.

» **Documents folder** - contains Microsoft Word documents and templates, images, and other binary objects that do not belong in one of the other folders.

» **Global Contexts and Context Associations** - Global Contexts are column mappings that users can configure for use throughout Phoenix. Context associations allow a user to define mappings at an operational object level.

» **Grid tab -** the tab in Phoenix used to display all worksheets.

» **Lattice** - a way to sort and display a group of plots on one panel instead of displaying them on multiple panels. Lattice plots are sometimes referred to as trellis plots. The maximum number of columns or rows in a latticed plot is 15 per page.

» **Mapping -** a method of assigning study variables and output parameters to inputs, or context associations, in an operational object. For example, the nominal sample time and plasma concentration columns in a data set can be mapped to the Time and Concentration inputs in a noncompartmental analysis object.

– When mapping values to context associations in an operational object, users must assign the appropriate data types, or variables or parameters, to the relevant context associations, or inputs. For example, time values in a study can be mapped to the time context association in an operational object.

» **MDI** - **M**ultiple **D**ocument **I**nterface. Allows users to open operational objects and worksheets in their own windows separate from the Phoenix main interface.

» **Object level view** - at the object level view, only the setup options and output results relating to a particular operational object are seen by the user.

» **Operational Objects** - objects that are used to perform a specific procedure such as noncompartmental analysis, descriptive statistics, data plotting, and worksheet operations such as worksheet merges.

» **Phoenix Modeling Language (PML) -** model coding language in Phoenix that uses S-PLUS and C++ syntax and is comparable to NONMEM. PML replaces the WinNonlin ASCII model language.

» **Plug-ins** - system functions that are made available to a user depending on the license type purchased, such as a Connect, WinNonlin, or an NLME

license. System functions include drug modeling, statistical calculations, and data manipulation.

» **Project** - a project can contain multiple workflows which can include multiple operational objects and data sets. A project is similar to a workspace in WinNonlin and a scenario in PKS.

» **Right viewing panel** - the main panel in Phoenix that shows the setup options for any item that is selected in the Object Browser. This includes operational objects, data sets, and items contained in the Code, Tables, and BQL folders.

» **Setup tab -** allows users to select from a list of options in order to set up an operational object to perform its function.

» **Tables folder** - contains HTML tables created by the Table object.

» **Templates -** operational objects and procedures in a workflow can be saved as a template that can be re-applied and re-run with different data sets. Templates do not save mappings to external data sets. Templates eliminate the need to recreate a set of operational procedures each time the same type of analysis or procedure has to be performed.

» **Workbook** - used to contain multiple worksheets. However, the Data folder can contain multiple worksheets without using a workbook.

» **Workflow** - an object that contains operational objects. Workflows can be set up to perform operational procedures using operational objects. In Phoenix, a workflow is two things: a term used to describe the flow of work in a project and an operational object used to group together other operational objects. A workflow operational object can be used to create a template.

» **Workflow level view** - the workflow level view provides a schematic of all operational objects and procedures in a workflow. Selecting a workflow allows a user to see the diagram of all objects, and the main setup panels and results for all objects.

» **Worksheet** - the fundamental data container used by Phoenix, and is similar to a Microsoft® Excel worksheet. Phoenix can create internal worksheets to contain data such as dosing values. Worksheets are mapped to operational objects as inputs and new worksheets are created to contain the results of object calculations. Just like in Excel, multiple worksheets can be combined into a workbook.

  – Several of Phoenix's operational objects can use external worksheets, which must be imported into Phoenix, and internal worksheets, which

are created in an operational object and can be published to the Data folder.

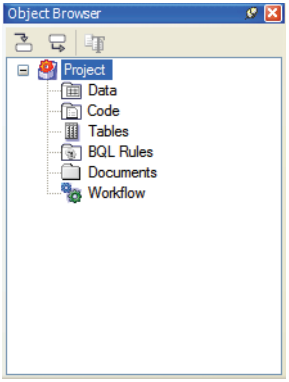
Phoenix Work Concepts

Work in Phoenix involves five important organizational concepts: projects, workflows, operational objects, templates, and data. Each of these concepts are explained in the following sections.

Projects

Projects contain all imported binary objects and all operational objects that are used to perform an analysis. Two of the benefits of Phoenix projects is that they allow analysis work to be easily organized and saved. Users can save projects as Phoenix project files (*.phxproj) or save them to PKS.

Default new project view



Phoenix projects contain the following items:

- a Data folder for worksheets and other data sets
- a Code folder for PML, ASCII, and NONMEM code
- a BQL Rules folder for BQL rules
- a Documents folder for binary objects not placed in the other folders
- a Workflow object that is used to group operational objects

» A Phoenix project is the workspace in which workflows, operational objects and worksheets are combined to perform an analysis. A Phoenix project can contain one or more independent or connected workflows, operational objects and worksheets.

» Phoenix projects are designed to be easily updated and shared, which allows for better data management. Phoenix projects can be saved locally or to a database and transferred between multiple users.

» A Phoenix project file contains all the data sets, such as study data, that were imported into a project. Project files can be exchanged between users without also having to exchange external data sources.

» Sharing Phoenix projects has two main advantages:
  – multiple users can review the steps and processes used in an analysis
  – the amount of time needed to validate the results of an analysis is decreased.

» In order for Phoenix projects to be easily updated, some functionality that was present in WinNonlin is no longer directly available in Phoenix. For example, worksheet formula support is now handled in Microsoft Excel through a custom export feature.

» **Phoenix does not automatically save projects**. Users must choose to save the project. Phoenix also prompts users to save projects when the application is closed. By default, Phoenix project files are saved in C:\Documents and Settings\<user name>\My Documents\Pharsight Projects.

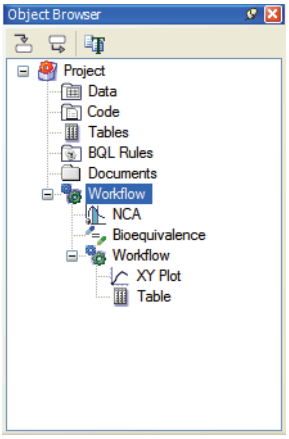
Workflows

There are two types of workflows: **project** and **operational**. The first type of workflow, the project workflow, refers to the series of steps needed to complete an analysis. This includes importing data, manipulating data, using model objects to analyze data, and saving or exporting the results.

The second type of workflow is an operational object. The workflow operational object is the root of all analysis work in Phoenix. Noncompartmental analysis,

PK analysis, and any other models that Phoenix supports are added to the workflow object.

Root workflow with a sub-workflow



What in Phoenix can be considered a workflow?

» A project and all its data, models, and output, can be a workflow.
  – Project workflows contain the data, models, and other objects needed to complete an analysis, from data setup through reporting of results.

» A workflow is an operational object that is used to group other operational objects.
  – The workflow operational object is a container for operational objects.
  – In a complex analysis that requires a large number of operational objects, workflows provide a way of organizing various operational objects into larger, more complex functional units.

Workflows as operational objects

Workflow objects can be inserted into a project like any other operational object. Multiple workflow objects can be added to a project's root workflow object. Each subsequent workflow object can contain its own group of operational objects.

What are the purposes of a workflow operational object?

» The workflow object acts as a container for other operational objects, such as an NCA object or a PK model object.

» Workflow objects allow users to put together as many types of operational objects as needed to complete an analysis.

» Workflow objects allow users to execute only a certain group of operational objects in a project.

» They allow users to access the Diagram tab, which can be used to add operational objects, map data, and execute objects.

» They allow users to map data and code to operational objects in the workflow, and to manage the flow of data between operational objects.

What are the differences between a workflow operational object and other operational objects?

» A workflow operational object does not perform any sort of analysis.

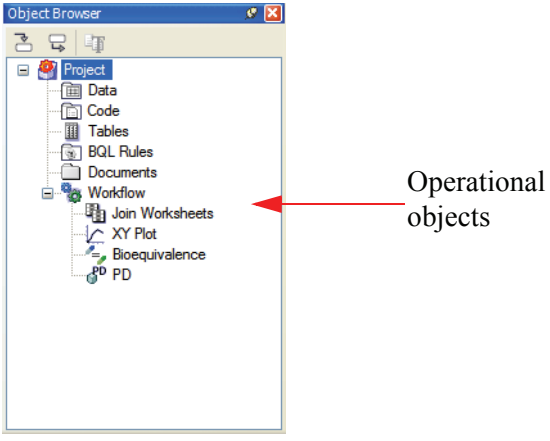
» All basic Phoenix operations such as NCA, NLME, or Convolution are operational objects, but are not workflows.

» A workflow operational object is used to group basic Phoenix operations for later use or reuse.

Operational Objects

Phoenix analysis work is done using operational objects. An operational object contain a pointer to input data, a model, plot, or some other function, plus worksheet results, plot results, and text results.

Operational objects in a workflow



What are the types of operational objects?

Examples of operational objects include data manipulation objects such as Column Transformation and Pivot Worksheet, models like Semicompartmental Modeling and PK Models, and plots like the XY Plot.

What types of data do operational objects use?

» Operational objects use two types of data: external and internal.

» An external data source for an operational object points to an imported data set in the Data folder. The data is not contained in the object.

» Internally generated data sources include worksheets created within Phoenix. These can be created either by users or by executing an operational object to get output results. These data are also not contained in the object.

» The output of one operational object can be connected to the input of another operational object to perform a series of calculations based on the other object's results. For example, the Final Parameters worksheet from a model can be sent to a Descriptive Stats object for further analysis.

How are operational objects used?

» All operational objects can be inserted from the Insert menu, the Object toolbox, the Send To menu, and the workflow menu.

» Operational objects have user-defined settings and options that can be accessed in the Setup tab list and in the option tabs located beneath the Setup tab.

» Operational objects have results in the form of worksheets, plots, and text, which are output from an executed operational object.

An operational object:

» is an operational function that accepts input data, has user-defined settings, and gives output results

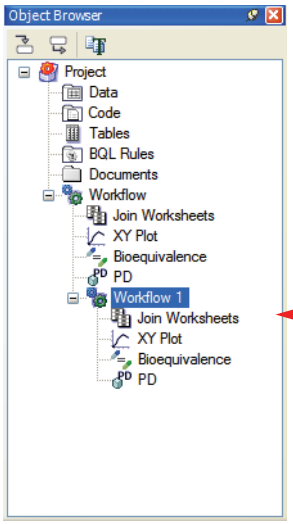
» has links to objects in the Data, Code, or BQL Rules folder, or has links to other operational objects

» is added to the workflow object in a project.

Templates

A template in Phoenix works like a template in Microsoft® Word - it allows users to recreate the same steps over and over, and gives users a form or fields that can be used to automatically recreate a workflow to use with a new data set.

Workflow added from a template file



Templates are files that contain the settings used with a workflow or operational object. Templates are saved as WinNonlin Template (*.wnlt) files.

Templates can be created to expedite future analysis for workflows and operational objects that are created to perform complex or specific functions. Templates contain the specific configuration of each operational object in a workflow, but do not contain the original data input sources.

CAUTION: Templates do not save any mappings or links to external data sources, which means templates lose data mappings to external sources.

What does a template do?

» Saves a workflow operational object, and all the operational objects it contains.

» Saves an individual operational object and its settings.

» Saves pointers to results data, such as a Final Parameters worksheet.

How are templates different from workflows and objects?

» Templates do not store pointers to non-results data, such as imported worksheets.

» Workflows and objects contain pointers to data sets, but templates do not.

How are templates different from project files?

» Project files save all parts of the project - all the data sets, code, rule sets, other information objects, and all workflows and operational objects.

» Templates save the setup information for workflow and operational objects, and any pointers to an operational object's results data.

What are the benefits of a template?

» A workflow can be saved as a template, in order to reapply an analysis on new data. This allows a common analysis to be pre-defined for automated performance of repetitive analyses.

» Users can perform the same operations on different data sets without having to recreate the original workflow that is saved in the template.

» Templates can be imported into a workflow, although templates do not save any data sets or data mappings.

Note: When a template is imported into a workflow, it is necessary to remap any external data sources to objects in the template.

Data

When a data set is imported into Phoenix, whatever changes are made to those data only affects the data that is imported into Phoenix. The actual file that contains the data is not affected.

This means that any changes made to data sets imported into Phoenix are not reflected in the data set that is saved on a hard drive or other storage media. Users can make as many changes as they want to a data set in Phoenix without changing the original data set.

What types of data does Phoenix use?

» Imported data sets such as worksheets and workbooks.

» User-created worksheets and workbooks.

» Worksheets that are the results of operational objects.

How is data used in Phoenix?

» The Data folder contains all the imported or created data sets that are used in a project.

» All data sets used in a workflow are contained internally within Phoenix.

» Changes made to imported data sets do not change the original data set.

» Data must be mapped to an operational object before it can be used.

Data mapping

Data mapping is the process of associating a data set with an operational object so that objects can use the data in an analysis or other function. Data mapping in Phoenix is as simple as dragging a data set from the Data folder to an object's input, or using the Select Object dialog to select a data set.

There are two types of data mapping in Phoenix: mapping data to an object, and mapping the variables or parameters in the data set to an object's contexts.

Mapping to an object:

» Data sets can be mapped to the different panels in an object's Setup list, or they can be mapped to an object's inputs in the Diagram tab.

Mapping to a context:

» Context mapping is the process of linking a specific column in a data set to a specific context in an operational object, such as Time or Concentration.

» Phoenix can complete context mappings if a column header in a worksheet matches the context name in an operational object.

» The Global Contexts and Context Association panels in the Preferences dialog can be used to automatically associate columns in a data set with contexts in an operational object.

  – For example, Phoenix can be set to automatically map a concentration column named conc to an operational object's concentration context.

Index

Numerics

10019, server error, 28

C

Create Template button, 68
Customer support, 1
    licensing, 1

D

Diagram tab, 69

H

History tab, 73

I

Information tab, 72
Installing
    WinNonlin, 5

L

Licensing
    customer support, 1

M

Main menu
    Edit, 65
    File, 65
    Help, 65
    Insert, 65
    PKS, 65
    Send To, 65
    Window, 65

O

Object Browser, 67
    BQL Rules folder, 67
    Code folder, 67
    Data folder, 67
    Documents folder, 68
    Operational object, 68
    Project, 67
    Tables folder, 67
    Workflow object, 68

P

Pharsight
    contact information, 1
Phoenix menu bar, 65
Phoenix User Interface, 63

R

Results tab, 71

S

Setup tab, 69
Show Dependents button, 68
Show Sources button, 68

T

Technical support, 1
    licensing, 1
Toolbar
    Copy, 66
    Cut, 66
    Delete, 66
    Execute, 67
    Export, 66
    Freeze panes, 66
    Import, 65
    Insert Column, 66
    Insert Row, 66
    Paste, 66
    Verify, 67

U

User interface, 63

V

Verification tab, 72

W

WinNonlin
    installing, 5